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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR

THE NORTHERN DISTRICT OF ALABAMA

AMERICA'S FRONTLINE DOCTORS, et al., Plaintiffs, vs. XAVIER BECERRA, Secretary of the U.S. Department of Health and Human Services, et al., Defendants.	)	Civil Action No. 2:21-cv-00702-CLM

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PLAINTIFFS MOTION FOR

PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called "Pfizer-BioNTech COVID-19 Vaccine,"[1] "Moderna COVID-19 Vaccine"[2] and the "Johnson & Johnson (Janssen) COVID-19 Vaccine"[3] (collectively, the "Vaccines")[4] pursuant to their respective EUAs, and from granting full Food and Drug Administration ("FDA") approval of the Vaccines:

(i) for the under-18 age category;

(ii) for those, regardless of age, who have been infected with SARS-CoV-2 prior to vaccination; and

(iii) until such time as the Defendants have complied with their obligation to create and maintain the requisite "conditions of authorization" under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb–3(e), thereby enabling Vaccine candidates to give truly voluntary, informed consent.

II. SUMMARY OF FACTS

Plaintiffs reference and incorporate herein the facts contained in their Complaint filed on June 10, 2021 (ECF 10).

A. <u>The Unlawful Vaccine Emergency Use Authorizations</u>

(1) 21 U.S.C. § 360bbb–3(b)(1)(C): There is No Emergency

On February 4, 2020, the Department of Health and Human Services ("DHHS") Secretary declared, pursuant to § 360bbb–3(b)(1)(C), that SARS-CoV-2 created a "public health

[1] Emergency Use Authorization ("EUA") issued December 11, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.

[2] EUA issued December 18, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.

[3] EUA issued February 27, 2021. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.

[4] For the sake of clarity of reference, Plaintiffs are using the names given to the Pfizer and Moderna EUA medical products by their manufacturers and the Defendants. However, Plaintiffs reject the highly misleading use of the term "vaccine" to describe the Pfizer and Moderna EUA medical products, since they are not vaccines within the settled meaning of the term and instead are more precisely described as a form of genetic manipulation.

emergency." This initial emergency declaration has been renewed repeatedly and remains in force today. The emergency declaration is the necessary legal predicate for the issuance of the Vaccine EUAs, which have allowed the mass use of the Vaccines by the American public, even before the completion of the standard regimen of clinical trials and FDA approval.

The emergency declaration and its multiple renewals are illegal, since in fact there is no underlying emergency. Assuming the accuracy of Defendants' COVID-19 death data, SARS-CoV-2 has an overall survivability rate of 99.8% globally, which increases to 99.97% for persons under the age of 70, on a par with the seasonal flu. However, Defendants' data is deliberately inflated. On March 24, 2020, DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations — **exclusively for COVID-19**. The rule change states: "COVID-19 should be reported on the death certificate for all decedents where the disease caused *or is assumed to have caused or contributed* to death." In fact, DHHS statistics show that 95% of deaths classed as "COVID-19 deaths" involve an average of four additional co-morbidities. The CDC knew "…the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not."

Similarly, the actual number of COVID-19 "cases" is far lower than the reported number. DHHS authorized the emergency use of the polymerase chain reaction ("PCR") test as a diagnostic tool for COVID-19, with disastrous consequences. The PCR tests are themselves experimental products, authorized by the FDA under separate EUAs. PCR test manufacturers use disclaimers like this in their product manuals: "[t]he FDA has not determined that the test is safe or effective for the detection of SARS-Co-V-2." Manufacturer inserts furnished with PCR test products include disclaimers stating that the PCR tests should NOT be used to diagnose

COVID-19. This is consistent with the warning issued by the Nobel Prize winning inventor of the PCR test that such tests are not appropriate for diagnosing disease.

The way in which the PCR tests are administered guaranties an unacceptably high number of false positive results. Cycle Threshold Value ("CT value") is essentially the number of times that a sample (usually from a nasal swab) is magnified or amplified before a fragment of viral RNA is detected. The CT Value is exponential, and so a 40-cycle threshold means that the sample is magnified around a trillion times. The higher the CT Value, the less likely the detected fragment of viral RNA is intact, alive and infectious.[5]

Virtually all scientists, including Dr. Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless. Dr. Fauci has stated (emphasis below added):

> ***What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule****…We have patients, and it is very frustrating for the patients as well as for the physicians…somebody comes in and they repeat their PCR and it's like 37 cycle threshold…you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it's dead nucleotides, period. In other words, it is not a COVID-19 infection.*[6]

A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at 35-45 cycles in accordance with manufacturer instructions. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted. The chart below shows that all major PCR tests in use in the United States are run at cycles of up to 35 or higher.

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[5] https://www.oralhealthgroup.com/features/the-problems-with-the-covid-19-test-a-necessary-understanding/ (last visited July 15, 2021).

[6] https://1027kearneymo.com/kpgz-news/2020/11/9/covid-tests-may-inflate-numbers-by-picking-up-dead-virus (last visited July 15, 2021).

Manufacturer	Manufacturer's Recommended Cycle Threshold
Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles
Opti Sars CoV-2 RT-PCR Test	45 cycles
Quest SARS-CoV-2rRT-PCR Test	40 cycles
CDC 2019-Novel Coronavirus Real Time (RT-PCR Diagnostic Panel) Test	40 cycles
Wren Labs COVID-19 PCR Test	38 cycles
LabCorp COVID-19 RT-PCR Test	35 cycles

Further, the Defendants and their counterparts in state governments used the specter of "asymptomatic spread" — the notion that fundamentally healthy people could cause COVID-19 in others — to justify the purported emergency. But there is *no credible scientific evidence* that demonstrates that the phenomenon of "asymptomatic spread" is real. On the contrary, on June 7, 2020, Dr. Maria Von Kerkhov, head of the WHO's Emerging Diseases and Zoonosis Unit, told a press conference that from the known research, asymptomatic spread was "very rare." "From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual." She added for emphasis: "it's very rare." Researchers from Southern Medical University in Guangzhou, China, published a study in August 2020 concluding that asymptomatic transmission of COVID-19 is *almost non-existent*. "Asymptomatic cases were least likely to infect their close contacts," the researchers found. A more recent study involving nearly 10 million residents of Wuhan, China found that there were no — zero — positive COVID-19 tests amongst 1,174 *close contacts* of asymptomatic cases, *indicating the complete absence of asymptomatic transmission*.

On September 9, 2020, Dr. Fauci was forced to admit in an official press conference:

> *[E]ven if there is some asymptomatic transmission, in all the history of respiratory borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person,*

> *even if there is a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers.*[7]

(2) § 360bbb–3(c)(1): There is in Fact no Serious or Life-Threatening Disease or Condition

Once an emergency has been declared and while it remains in force, the DHHS Secretary can issue and maintain EUAs "**only if**" (emphasis added) certain criteria are met. One of these criteria is that there is in fact (not simply perceived, projected or declared) "a serious or life threatening disease or condition." For the reasons set forth above in the prior section, SARS-CoV-2 and COVID-19 do not constitute a "serious or life threatening disease or condition" within the meaning of the statute. It also bears noting that the legal purpose of an emergency declaration is to bypass checks and balances typically required under law due to a crisis and that the use of such a declaration for such an arbitrary purpose could undermine the balance of power between the various branches of government.

(3) § 360bbb–3(c)(2)(A): The Vaccines Do Not Diagnose, Treat or Prevent SARS-CoV-2 or COVID-19

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" they are "effective" in diagnosing, treating or preventing a disease or condition.

Centers for Disease Control and Prevention ("CDC") data shows that the Vaccines are not effective in treating or preventing SARS-CoV-2 or COVID-19. Deaths from COVID-19 in those who have received the recommended dosages of the Vaccines increased from 160 as of April 30, 2021 to 535 as of June 1, 2021. Further, a total of 10,262 SARS-CoV-2 "breakthrough infections" of those who have already received the full recommended dosage of the Vaccines

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[7] https://www.statnews.com/2021/01/23/asymptomatic-infection-blunder-covid-19-spin-out-of-control/ (last visited July 15, 2021).

were reported to the CDC from 46 states and territories between January 1, 2021 and April 30, 2021.

In studying the effectiveness of a medical intervention in randomized controlled trials (often called the gold standard of study design), the most useful way to present results is in terms of Absolute Risk Reduction ("ARR"). ARR compares the impact of treatment by comparing the outcomes of the treated group and the untreated group. In other words, if 20 out of 100 untreated individuals had a negative outcome, and 10 out of 100 treated individuals had a negative outcome, the ARR would be 10% (20 - 10 = 10). **According to a study published by the NIH, the ARR for the Pfizer Vaccine is a mere 0.7%, and the ARR for the Moderna Vaccine is only 1.1%.**

From the ARR, one can calculate the Number Needed to Vaccinate ("NNV"), which signifies the number of people that must be injected before even one person benefits from the vaccine. The NNV for the Pfizer Vaccine is 119, meaning that 119 people must be injected in order to observe the reduction of a COVID-19 case in one person. The reputed journal the *Lancet* reports data indicating that the NNV may be as high as 217.

There are several factors that reduce any purported benefit of the COVID-19 Vaccines. First, it is important to note that the Vaccines were only shown to reduce symptoms – not block transmission. For over a year now, these Defendants and state-level public health authorities have told the American public that SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19, therefore Americans must mask themselves, and submit to innumerable lockdowns and restrictions, even though they are not manifestly sick. If that is the case, and these officials were not lying to the public, and asymptomatic spread is real, then what is the benefit of a vaccine that merely reduces symptoms? There isn't any.

Secondly, it appears that these Defendants either did lie about asymptomatic spread, or were simply wrong about the science. The theory of asymptomatic transmission — used as the justification for the lockdown and masking of the healthy — was based *solely* upon mathematical modeling. This theory had no actual study participants, and no peer review. The authors made the unfounded assumption that asymptomatic persons were "75% as infectious" as symptomatic persons. But in the real world, healthy false positives turned out to be merely healthy, and were never shown to be "asymptomatic" carriers of anything. Studies have shown that PCR test-positive asymptomatic individuals do not induce clinical COVID-19 disease, not even in a family member with whom they share a home and extended proximity. An enormous study of nearly ten million people in Wuhan, China showed that asymptomatic individuals testing positive for COVID-19 **never** infected others. Since asymptomatic individuals do not spread COVID-19, they do not need to be vaccinated.

(4) § 360bbb–3(c)(2)(B): The Known and Potential Risks of the Vaccine Outweigh their Known and Potential Benefits

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" (emphasis added) the known and potential risks of each Vaccine are outweighed by its known and potential benefits.

The typical vaccine development process takes between 10 and 15 years, and consists of the following sequential stages: research and discovery (2 to 10 years), pre-clinical animal studies (1 to 5 years), clinical human trials in four phases (typically 5 years). Phase 1 of the clinical human trials consists of healthy individuals and is focused on safety. Phase 2 consists of additional safety and dose-ranging in healthy volunteers, with the addition of a control group. Phase 3 evaluates efficacy, safety and immune response in a larger volunteer group, and requires two sequential randomized controlled trials. Phase 4 is a larger scale investigation into longer-

term safety. Vaccine developers must follow this process in order to be able to generate the data the FDA needs in order to assess the safety and effectiveness of a vaccine candidate.

This 10-15 year testing process has been abandoned for purposes of the Vaccines. The first human-to-human transmission of the SARS-CoV-2 virus was not confirmed until January 20, 2020, and less than a year later both mRNA Vaccines had EUAs and for the first time in history this novel mRNA technology was being injected into millions of human beings. As of June 7, 2021, 138 million Americans, representing 42% of the population, have been fully vaccinated.

All of the stages of testing have been compressed in time, abbreviated in substance, and are overlapping, which dramatically increases the risks of the Vaccines. Plaintiffs' investigation indicates that Moderna and Pfizer designed their Vaccines in only two days. It appears that pharmaceutical companies did not independently verify the genome sequence that China released on January 11, 2020. It appears that the Vaccines were studied for only 56 days in macaques, and 28 days in mice, and then animal studies were halted. It appears that the pharmaceutical companies discarded their control groups receiving placebos, squandering the opportunity to learn about the rate of long-term complications, how long protection against the disease lasts and how well the Vaccines inhibit transmission. A number of studies were deemed unnecessary and not performed prior to administration in human subjects, including single dose toxicity, toxicokinetic, genotoxicity, carcinogenicity, prenatal and postnatal development, offspring, local tolerance, teratogenic and postnatal toxicity and fertility. The American public has not been properly informed of these dramatic departures from the standard testing process, and the risks they generate.

Plaintiff America's Frontline Doctors' ("AFLDS") medico-legal researchers have analyzed the accumulated COVID-19 Vaccine risk data, and report as follows:

Migration of the SARS-CoV-2 "Spike Protein" in the Body

The SARS-CoV-2 has a spike protein on its surface. The spike protein is what allows the virus to infect other bodies. It is clear that the spike protein is not a simple, passive structure. The spike protein is a "pathogenic protein" and a toxin that causes damage. The spike protein is itself biologically active, even without the virus. It is "fusogenic" and consequently binds more tightly to our cells, causing harm. If the purified spike protein is injected into the blood of research animals, it causes profound damage to their cardiovascular system, and crosses the blood-brain barrier to cause neurological damage. If the Vaccines were like traditional *bona fide* vaccines, and did not leave the immediate site of vaccination, typically the shoulder muscle, beyond the local draining lymph node, then the damage that the spike protein could cause might be limited.

However, the Vaccines were authorized without any studies demonstrating where the spike proteins traveled in the body following vaccination, how long they remain active and what effect they have. A group of international scientists has recently obtained the "biodistribution study" for the mRNA Vaccines from Japanese regulators. The study reveals that unlike traditional vaccines, this spike protein enters the bloodstream and circulates throughout the body over several days post-vaccination. It accumulates in a number of tissues, such as the spleen, bone marrow, liver, adrenal glands and ovaries. It fuses with receptors on our blood platelets, and also with cells lining our blood vessels. It can cause platelets to clump leading to clotting, bleeding and heart inflammation. It can also cross the blood-brain barrier and cause brain damage. It can be transferred to infants through breast milk. The VAERS system includes reports of infants suckling from vaccinated mothers experiencing bleeding disorders in the gastrointestinal tract.

<u>Increased Risk of Death from Vaccines</u>

The government operated VAERS database is intended to function as an "early warning" system for potential health risks caused by vaccines. It is broadcasting a red alert. Of the 262,000 total accumulated reports in VAERS, only 1772 are not related to COVID-19. The database indicates that the total reported vaccine deaths in the first quarter of 2021 represents a 12,000% to 25,000% increase in vaccine deaths, year-on-year. In ten years (2009-2019) there were 1529 vaccine deaths, whereas in the first quarter of 2021 there have been over 4,000. Further, 99% of all reported vaccine deaths in 2021 are caused by the COVID-19 Vaccines, only 1% being caused by the numerous other vaccines reported in the system. It is estimated that VAERS only captures 1% to at best 10% of all vaccine adverse events.

<u>Reproductive Health</u>

The mRNA Vaccines induce our cells to manufacture (virus-free) "spike proteins." The "spike proteins" are in the same family as the naturally occurring syncytin-1 and syncytin-2 reproductive proteins in sperm, ova and placenta. Antibodies raised against the spike protein might interact with the naturally occurring syncytin proteins, adversely affecting multiple steps in human reproduction. The manufacturers did not provide data on this subject despite knowing about the spike protein's similarity to syncytin proteins for more than one year. There are now a very high number of pregnancy losses in VAERS. A study recently published in the New England Journal of Medicine, "Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons," exposes that pregnant women receiving Vaccines during their first or second trimesters suffer an 82% spontaneous abortion rate, killing 4 out of 5 unborn babies. There are worldwide reports of irregular vaginal bleeding without clear explanation. Scientists are concerned that the Vaccines pose a substantial risk to a woman's reproductive system. This increased risk of sterility stems from an increased concentration of the spike proteins in various

parts of the reproductive system after vaccination. Not enough is known to determine the risk of sterility, but it is beyond question that the risk is increased.

A leaked Pfizer document (excerpted below) exposes that Pfizer Vaccine nanoparticles accumulate in the ovaries at an extraordinarily high rate, in concentrations orders of magnitude higher than in other tissues. Billions of aggressive spike proteins are accumulating in very delicate ovarian tissues, the one place in the human body where females carry a finite number of fertile eggs.

SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048)
2.6.5 薬物動態試験の概要表

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED **Test Article: [**

Sample	Total Lipid concentration (μg lipid equivalent/g [or mL]) (males and females combined)							%
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--

PFIZER CONFIDENTIAL
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Each baby girl is born with the total number of eggs she will ever have in her entire life. Those eggs are stored in the ovaries, and one egg is released each month of a normal menstrual cycle. When there are no more eggs, a woman stops menstruating. The reproductive system is

arguably the most delicate hormonal and organ balance of all our systems. The slightest deviation in any direction results in infertility. Even in 2021, doctors and scientists do not know all the variables that cause infertility.

There is evidence to support that the Vaccines could cause permanent autoimmune rejection of the placenta. Placental inflammation resulting in stillbirths mid-pregnancy (second trimester) is seen with COVID-19 and with other similar coronaviruses. There is a case report of a woman with a normally developing pregnancy who lost the otherwise healthy baby at five months during acute COVID-19. The mother's side of the placenta was very inflamed. This "infection of the maternal side of the placenta inducing acute or chronic placental insufficiency resulting in miscarriage or fetal growth restriction was observed in 40% of pregnant women with similar coronaviruses." The mRNA Vaccines may instigate a similar reaction as the SARS-CoV-2 virus. There is a component in the vaccine that could cause the same autoimmune rejection of the placenta, but indefinitely. Getting COVID-19 has been associated with a high risk of mid-pregnancy miscarriage because the placenta fails. The mRNA Vaccines may have precisely the same effect, however, not for just the few weeks of being sick, but forever. Repeated pregnancies would keep failing in mid-pregnancy.

On December 1, 2020, a former Pfizer Vice President and allergy and respiratory researcher, Dr. Michael Yeadon, filed an application with the European Medicines Agency, responsible for approving drugs in the European Union, seeking the immediate suspension of all SARS-CoV-2 Vaccines, citing *inter alia* the risk to pregnancies. As of April 26, 2021, the VAERS database contains over 3,000 reports of failed pregnancies associated with the Vaccines.

<u>Vascular Disease</u>

Salk Institute for Biological Studies researchers in collaboration with the University of San Diego, published in the journal *Circulation Research* that the spike proteins themselves

damage vascular cells, causing strokes and many other vascular problems. All of the Vaccines are causing clotting disorders (coagulopathy) in all ages. The spike proteins are known to cause clotting that the body cannot fix, such as brain thrombosis and thrombocytopenia.

None of these risks has been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Autoimmune Disease

The spike proteins are perceived to be foreign by the human immune system, initiating an immune response to fight them. While that is the intended therapeutic principle, it is also the case that any cell expressing spike proteins becomes a target for destruction by our own immune system. This is an autoimmune disorder and can affect virtually any organ in the body. It is likely that some proportion of spike protein will become permanently fused to long-lived human proteins and this will prime the body for prolonged autoimmune diseases. Autoimmune diseases can take years to show symptoms and many scientists are alarmed at giving young people such a trigger for possible autoimmune disease.

Neurological Damage

The brain is completely unique in structure and function, and therefore it requires an environment that is insulated against the rest of the body's functioning. The blood-brain-barrier exists so the brain can function without disruption from the rest of the body. This is a complex, multi-layered system, using several mechanisms that keep nearly all bodily functions away from the brain. Three such systems include: very tight junctions between the cells lining the blood vessels, very specific proteins that go between, and unique enzymes that alter substances that do go through the cells. Working together, the blood-brain-barrier prevents almost everything from getting in. Breaching it is generally incompatible with life.

Most unfortunately, the COVID-19 Vaccines — unlike any other vaccine ever deployed — are able to breach this barrier through various routes, including through the nerve structure in the nasal passages and through the blood vessel walls. The resulting damage begins in the arterial wall, extends to the supporting tissue outside the arteries in the brain, and from there to the actual brain nerve cells inside. The Vaccines are programmed to produce the S1 subunit of the spike protein in every cell in every Vaccine recipient, but it is this subunit that causes the brain damage and neurologic symptoms. Elderly persons are at increased risk for this brain damage.

COVID-19 patients typically have neurological symptoms including headache and loss of smell and taste, as well as brain fog, impaired consciousness, and stroke. Researchers have published a paper in the *Journal of Neurological Sciences* correlating the severity of the pulmonary distress in COVID-19 with viral spread to the brain stem, suggesting direct brain damage, not just a secondary cytokine effect. It has been shown recently by Dr. William Banks, professor of Internal Medicine at University of Washington School of Medicine, that the S1 subunit of the spike protein — the part of the SARS-CoV-2 virus that produces the COVID-19 disease and is in the Vaccines — can cross the blood brain barrier. This is even more concerning, given the high number of ACE2 receptors in the brain (the ACE2 receptor is that portion of the cell that allows the spike protein to connect to human tissue). Mice injected with the S1 subunit of the spike protein developed direct damage to the perivascular tissue. In humans, viral spike protein was detected in the brain tissues of COVID-19 patients, but not in the brain tissues of the controls. Spike protein produces endothelial damage.

There are an excessive number of brain hemorrhages associated with COVID-19, and the mechanism suggests that it is the spike protein that is responsible. The federal government's VAERS database shows a dramatic increase in adverse event reporting of neurological damage following injection with the Vaccine.

Year	**Dementia** (reports following injection with Vaccine)	**Brain Bleeding** (reports following injection with Vaccine)
2000	4	7
2010	0	17
2015	0	17
2018	21	31
2019	11	17
2020	12 → (43)	4 → (11)
2021	17 → (251)	0 → (258)

While the full impact of these Vaccines crossing the blood-brain barrier is unknown, they clearly put vaccinated individuals at a substantially increased risk of hemorrhage, neurological damage, and brain damage as demonstrated by the increased instances of such reporting in the VAERS system.

Effect on the Young

The Vaccines are more deadly or harmful to the young than the virus, and that is excluding the unknown future effects on fertility, clotting, and autoimmune disease. Those under the age of 18 face statistically zero chance of death from SARS-CoV-2 according to data published by the CDC, but there are reports of heart inflammation — both myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) — in young men, and at least one documented fatal heart attack of a healthy 15-year old boy in Colorado two days after receiving the Pfizer Vaccine.[8] The CDC has admitted that "[s]ince April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after the mRNA COVID-19 vaccination (Pfizer-BioNTech and Mederna), particularly in adolescents and young adults."

[8] https://archive.is/mEBcV (last visited July 15, 2021).

The Vaccines induce the cells of the recipient to manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, a very strong immune response, including those which can damage their own cells and tissues, including by stimulating blood coagulation.

See also infra Section II.B.

Chronic Disease

Healthy children whose birthright is decades of healthy life will instead face premature death or decades of chronic disease. We cannot say what percentage will be affected with antibody dependent enhancement, neurological disorders, autoimmune disease and reproductive problems, but it is a virtual certainty that this will occur.

Antibody Dependent Enhancement

Antibody Dependent Enhancement ("ADE") occurs when SARS-CoV-2 antibodies, created by a Vaccine, instead of protecting the vaccinated person, cause a more severe or lethal case of the COVID-19 disease when the person is later exposed to SARS-CoV-2 in the wild.[9] The vaccine *amplifies* the infection rather than *preventing* damage. It may only be seen after months or years of use in populations around the world.

This paradoxical reaction has been seen in other vaccines and animal trials. One well-documented example is with the Dengue fever vaccine, which resulted in avoidable deaths. Dengue fever has caused 100-400 million infections, 500,000 hospitalizations, and a 2.5% fatality rate annually worldwide. It is a leading cause of death in children in Asian and Latin American countries. Despite over 50 years of active research, a Dengue vaccine still has not

[9] https://www.nature.com/articles/s41564-020-00789-5 (last visited July 15, 2021).

gained widespread approval in large part due to the phenomenon of ADE. Vaccine manufacturer Sanofi Pharmaceutical spent 20 years and nearly $2 billion to develop the Dengue vaccine and published their results in the *New England Journal of Medicine*, which was quickly endorsed by the World Health Organization. Vigilant scientists clearly warned about the danger from ADE, which the Philippines ignored when it administered the vaccine to hundreds of thousands of children in 2016. Later, when these children were exposed in the wild, many became severely ill and 600 children died. The former head of the Dengue department of the Research Institute for Tropical Medicine (RITM) was indicted in 2019 by the Phillipines Department of Justice for "reckless imprudence resulting [in] homicide," because he "facilitated, with undue haste," Dengvaxia's approval and its rollout among Philippine schoolchildren.[10]

ADE has been observed in the coronavirus setting. The original SARS-CoV-1 caused an epidemic in 2003. This virus is a coronavirus that is reported to be 78% similar to the current SARS-CoV-2 virus that causes the disease COVID-19. Scientists attempted to create a vaccine. Of approximately 35 vaccine candidates, the best four were trialed in ferrets. The vaccines appeared to work in the ferrets. However, when those vaccinated ferrets were challenged by SARS-CoV-1 in the wild, they became very ill and died due to what we would term a sudden severe cytokine storm. The reputed journals *Science*, *Nature* and *Journal of Infectious Diseases* have all documented ADE risks in relation to the development of experimental COVID-19 vaccines. The application filed by Dr. Yeadon with the European Medicines Agency on December 1, 2020 also mentioned the risk from ADE. ADE is discovered during long-term animal studies, to which the Vaccines have not been subjected.

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[10] https://trialsitenews.com/philippine-dengue-vaccine-criminal-indictments-includes-president-of-sanofi-pasteur-their-fda (last visited July 15, 2021).

Vaccine-Driven Disease Enhancement in the Previously Infected

See infra section II. C.

More Virulent Strains

Scientists are concerned that universal inoculation may create more virulent strains. This has been observed with Marek's Disease in chickens.[11] A large number of chickens not at risk of death were vaccinated, and now all chickens must be vaccinated or they will die from a virus that was nonlethal prior to widespread vaccination. The current policy to pursue universal vaccination regardless of risk may exert the same evolutionary pressure toward more highly virulent strains.

Blood Supply

Presently, the vaccinated are permitted to donate their spike protein laden blood into the blood supply, which projects all of the risks discussed *supra* onto the general population of unvaccinated blood donees.

Scientists and healthcare professionals all over the world are sounding the alarm and frantically appealing to the FDA to halt the Vaccines. They have made innumerable public statements. Fifty-seven top scientists and doctors from Central and South America are calling for an immediate end to all Vaccine COVID-19 programs. Other physician-scientist groups have made similar calls, among them: Canadian Physicians, Israeli People's Committee, Frontline COVID-19 Critical Care Alliance, World Doctors Alliance, Doctors 4 Covid Ethics, and Plaintiff America's Frontline Doctors. These are healthcare professionals in the field who are seeing the catastrophic and deadly results of the rushed Vaccines, and reputed professors of science and medicine, including the physician with the greatest number of COVID-19 scientific citations

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[11] https://en.wikipedia.org/wiki/Marek%27s_disease (last visited July 15, 2021).

worldwide. They accuse the government of deviating from long-standing policy to protect the public. In the past, government has halted vaccine trials based on a tiny fraction — far less than 1% — of the number of unexplained deaths already recorded. The scientists all agree that the spike protein (produced by the Vaccines) *causes disease even without the virus,* which has motivated them to lend their imprimatur to, and risk their reputation and standing on, these public objections.

(5) § 360bbb–3(c)(3): There Are Adequate, Approved and Available Alternatives to the Vaccines

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" (emphasis added) there is no adequate, approved and available alternative to the Vaccines.

There are numerous alternative safe and effective treatments for COVID-19. These alternatives are supported by over 300 studies, including randomized controlled studies. Tens of thousands of physicians have publicly attested, and many have testified under oath, as to the safety and efficacy of the alternatives. Globally and in the United States, treatments such as Ivermectin, Budesonide, Dexamethasone, convalescent plasma and monoclonal antibodies, Vitamin D, Zinc, Azithromycin, Hydroxychloroquine, Colchicine and Remdesivir are being used to great effect, and they are far safer than the COVID-19 Vaccines.[12]

Doctors from the Smith Center for Infectious Diseases and Urban Health and the Saint Barnabas Medical Center have published an *Observational Study on 255 Mechanically Ventilated COVID Patients at the Beginning of the USA Pandemic*, which states: "Causal modeling establishes that weight-adjusted HCQ [Hydroxychloroquine] and AZM [Azithromycin] therapy improves survival by over 100%."[13]

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[12] Numerous studies can be reviewed here: https://c19early.com (last visited June 7, 2021).

[13] https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1 (last visited July 15, 2021).

Observational studies in Delhi and Mexico City show dramatic reductions in COVID-19 case and death counts following the mass distribution of Ivermectin. These results align with those of a study in Argentina, in which 800 healthcare professionals received Ivermectin, while another 400 did not. Of the 800, not a single person contracted COVID-19, while more than half of the control group did contract it. Dr. Pierre Kory, a lung specialist who has treated more COVID-19 patients than most doctors, representing a group of some of the most highly published physicians in the world, with over 2,000 peer reviewed publications among them, testified before the U.S. Senate in December 2020.[14] He testified that based on 9 months of review of scientific data from 30 studies, Ivermectin obliterates transmission of the SARS-CoV-2 virus and is a powerful prophylactic (if you take it, you will not contract COVID-19). Four large randomized controlled trials totaling over 1500 patients demonstrate that Ivermectin is safe and effective as a prophylaxis. In early outpatient treatment, three randomized controlled trials and multiple observational studies show that Ivermectin reduces the need for hospitalization and death in statistically significant numbers. In inpatient treatment, four randomized controlled trials show that Ivermectin prevents death in a statistically significant, large magnitude. Ivermectin won the Nobel Prize in Medicine in 2015 for its impacts on global health.[15]

Inexplicably, the Defendants never formed or assigned a task force to research and review existing alternatives for preventing and treating COVID-19. Instead, the Defendants and others set about censoring both concerns about the Vaccines, and information about safe and effective alternatives.

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[14] https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwji38elkuPxAhWeAp0JHZhzAeMQFnoECAIQAA&url=https%3A%2F%2Fwww.hsgac.senate.gov%2Fdownload%2Fkory12-08-2020&usg=AOvVaw3z2a7PpDLWgyfSrp3miF1y (last visited July 15, 2021).

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692067/ (last visited July 15, 2021).

(6) § 360bbb–3(e)(1)(A)(i) and (ii): Healthcare Professionals and Vaccine Candidates are Not Adequately Informed

Once an EUA has been issued, § 360bbb–3(e) mandates that the DHHS Secretary "shall [ ] establish" conditions "designed to ensure" that both healthcare professionals and Vaccine candidates receive certain minimum required information that is necessary in order to make voluntary, informed consent possible. The required disclosures that the DHHS Secretary are designed to ensure include inter alia (i) that the Vaccines are only authorized for emergency use and not FDA approved, (ii) the significant known and potential risks of the Vaccines, (iii) available alternatives to the Vaccines, (iv) the option to accept or refuse the Vaccines.

<u>The Vaccines are Not Approved by the FDA, but Merely Authorized for Emergency Use</u>

Defendants have failed to educate the American public that the FDA has not actually "approved" the Vaccines, and that the DHHS Secretary has *not* in fact determined that the Vaccines are "safe and effective," and on the contrary has merely determined, in accordance with the proverbial "weasel language" of the EUA statute, that "**it is reasonable to believe**" that the Vaccines "**may be**" effective and that the benefits outweigh the risks. Instead of being so educated, the public is barraged with unqualified "safe and effective" messaging from all levels of federal and state government, the private sector and the media. They hear from no higher authority than the President himself that: "The bottom line is this: I promise you they are safe. They are safe. And even more importantly, they're extremely effective. If you're vaccinated, you are protected."

The public are also unaware of the serious financial conflicts-of-interest that burden Dr. Fauci, the National Institute of Allergies and Infectious Diseases, and the Vaccines and Related Biological Products Advisory Committee which advises and consults Defendants with respect to the Vaccine EUAs, as outlined in the Complaint (ECF 10, ¶¶ 250-256). Without the information

regarding conflicts-of interest, the public cannot assess for themselves the reliability and objectivity of the analysis underpinning the EUAs.

The Significant Known and Potential Risks of the Vaccines

Perhaps the first step in understanding the potential risks of the Vaccines is to understand exactly what they are, and what they are not. The CDC defines a "vaccine" as: "A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose."[16] The CDC defines "immunity" as: "Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."[17]

However, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" do not meet the CDC's own definitions. They do not stimulate the body to produce immunity from a disease. They are a synthetic fragment of nucleic acid embedded in a fat carrier that is introduced into human cells, not for the purpose of inducing immunity from infection with the SARS-CoV-2 virus, and not to block further transmission of the virus, but in order to lessen the symptoms of COVID-19. No published, peer-reviewed studies prove that the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" confer immunity or stop transmission.

Further, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" are not "vaccines" within the common, lay understanding of the public. Since vaccines were first discovered in 1796 by Dr. Edward Jenner, who used cowpox to inoculate humans against smallpox, and called the process "vaccination" (from the Latin term *vaca* for cow), the

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[16] *See* https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited July 9, 2021).
[17] Id.

public has had an entrenched understanding that a vaccine is a microorganism, either alive but weakened, or dead, that is introduced into the human body in order to trigger the production of antibodies that confer immunity from the targeted disease, and also prevent its transmission to others. The public are accustomed to these traditional vaccines and understand them.

The public are fundamentally uninformed about the gene therapy technology behind the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." Referring to the "mRNA technology" in its Vaccine, Moderna admits the "novel and unprecedented nature of this new class of medicines" in its Securities and Exchange Commission filings.[18] Further, it admits that the FDA classes its Vaccine as a form of "gene therapy." No dead or attenuated virus is used in the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." Rather, instructions, via a piece of lab-created genetic code (the mRNA) are injected into your body that tell your body how to make a certain "spike protein" that is purportedly useful in attacking the SARS-CoV-2 virus.

By referring to the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" as "vaccines," and by allowing others to do the same, the Defendants knowingly seduce and mislead the public, short-circuit independent, critical evaluation and decision-making by the consumers of these products, and vitiate their informed consent to this novel technology which is being deployed in the unsuspecting human population for the first time in history.

Meanwhile, the federal government is orchestrating a nationwide media campaign funded with $1 billion — not to ensure that the Defendants meet their statutory disclosure obligations, but solely to promote the purported benefits of the Vaccines. Simultaneously, the Associated Press, Agence France Press, British Broadcasting Corporation, CBC/Radio-Canada, European

[18] *See* www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm (last visited July 6, 2021).

Broadcasting Union (EBU), Facebook, Financial Times, First Draft, Google/YouTube, The Hindu Times, Microsoft, Reuters, Reuters Institute for the Study of Journalism, Twitter, The Washington Post and The New York Times all participate in the "Trusted News Initiative" which has agreed to not allow any news critical of the Vaccines.

Individual physicians are being censored on social media platforms (e.g., Twitter, Facebook, Instagram, TikTok), the modern day "public square." Plaintiff AFLDS has recorded innumerable instances of social media deleting scientific content posted by AFLDS members that runs counter to the prevailing Vaccine narrative, and then banning them from the platform altogether as users. Facebook has blocked the streaming of entire events at which AFLDS Founder Dr. Simone Gold has been an invited guest, prior to her uttering a word. Other doctors have been banned for posting or tweeting screenshots of government database VAERS.

The censorship also extends to medical journals. In an unprecedented move, the four founding topic editors for the *Frontiers in Pharmacology* journal all resigned together due to their collective inability to publish peer reviewed scientific data on various drugs for prophylaxis and treatment of COVID-19.

Dr. Philippe Douste-Blazy, a cardiology physician, former France Health Minister, 2017 candidate for Director of the WHO and former Under-Secretary-General of the United Nations, described the censorship in chilling detail:

> *The Lancet boss said "Now we are not going to be able to, basically, if this continues, publish any more clinical research data, because the pharmaceutical companies are so financially powerful today and are able to use such methodologies, as to have us accept papers which are apparently, methodologically perfect but in reality, which manage to conclude what they want to conclude." … one of the greatest subjects never anyone could have believed … I have been doing research for 20 years in my life. I never thought the boss of The Lancet could say that. And the boss of the New England Journal of Medicine too. He even said it was "criminal" — the word was used by him. That is, if you will, when there is an outbreak like the COVID-19, in reality, there are people … us,*

> *we see "mortality" when you are a doctor or yourself, you see "suffering." And there are people who see "dollars" — that's it.*

In many instances, highly publicized attacks on early treatment alternatives seem to be done in bad faith. For example, one study on Hydroxychloroquine overdosed study participants by administering a multiple of the standard prescribed dose, and then reported the resulting deaths as though they were not a result of the overdose, but from the medication itself administered in the proper dosages. The twenty-seven physician-scientist authors of the study were civilly indicted and criminally investigated, and still the Journal of the American Medical Association has not retracted the article.[19]

<u>The Available Alternatives to the Vaccines</u>

Information regarding available alternatives to the Vaccines has been suppressed and censored equally with information regarding the risks of the Vaccines, as aforesaid.

<u>The Option to Accept or Refuse the Vaccines</u>

The idea of using fear to manipulate the public is not new, and is a strategy frequently deployed in public health. In June 2020, three American public health professionals, concerned about the psychological effects of the continued use of fear-based appeals to the public in order to motivate compliance with extreme COVID-19 countermeasures, authored a piece for the journal *Health Education and Behavior* calling for an end to the fear-mongering. In doing so, they acknowledged that fear has become an accepted public health strategy, and that it is being deployed aggressively in the United States in response to COVID-19:

> *"… behavior change can result by increasing people's perceived severity and perceived susceptibility of a health issue through heightened risk appraisal coupled by raising their self-efficacy and response-efficacy*

[19] https://www.medrxiv.org/content/medrxiv/early/2020/04/16/2020.04.07.20056424.full.pdf (last visited July 15, 2021).

> *about a behavioral solution. In this model, fear is used as the trigger to increase perceived susceptibility and severity."*

In 1956, Dr. Alfred Biderman, a research social psychologist employed by the U.S. Air Force, published his study on techniques employed by communist captors to induce individual compliance from Air Force prisoners of war during the Korean War. The study was at the time and to some extent remains the core source for capture resistance training for the armed forces. The chart below compares the techniques used by North Korean communists with the fear-based messaging and COVID-19 countermeasures to which the American population has been subjected over the last year.

"COMMUNIST COERCIVE METHODS FOR ELICITING INDIVIDUAL COMPLIANCE".*
The Biderman Report of 1956 and COVID-19

Chart of Coercion	COVID-19
Isolation • Deprives individual of social support of his ability to resist • Makes individual dependent upon the captor • Individual develops an intense concern with self.	***Isolation*** • Social distancing • Isolation from loved ones, massive job loss • Solitary confinement semi-isolation • Quarantines, containment camps
Monopolization of Perception • Fixes all attention upon immediate predicament; • Frustrates all actions not consistent with compliance • Eliminates stimuli competing with those controlled by the captor	***Monopolization of perception*** • Restrict movement • Create monotony, boredom • Prevent gathering, meetings, concerts, sports • Dominate all media the 24/7, censor information
Induced Debility and Exhaustion • Weakens mental and physical ability to resist • People ...become worn out by tension and fear	***Induced debility*** • Forced to stay at home, all media is negative • not permitted to exercise or socialize
Threats • Cultivates anxiety and despair • Gives demands and consequences for non compliance	***Threats and Intimidation*** • Threaten to close business, levy fines • Predict extension of quarantine, force vaccines • Create containment camps
Occasional Indulgences • Provides motivation for compliance • Hinders adjustment to deprivation. • Creates hope for change, reduces resistance • This keeps people unsure of what is happening.	***Occasional Indulgences*** • Allow reopening of some stores, services • Let restaurants open but only at a certain capacity • Increase more people allowed to gather • Follow concessions with tougher rules
Demonstrate Omnipotence • Demonstrates futility of resistance • Shows who is in charge • Provides positive motivation for compliance	***Demonstrate Ominpotence*** • Shut down entire economies across the world • Create money out of nowhere, force dependency • Develop *total* surveillance with nanochips and 5G
Degradation • Makes resistance seem worse than compliance • Creates feelings of helplessness. • Creates fear of freedom, dependence upon captors	***Humiliation or Degradation techniques*** • Shame people who refuse masks, don't distance • Make people stand on circles and between lines • Make people stand outside and wait in queues • Sanitation stations in every shop
Enforcing trivial demands • Develops habit of compliance • Demands made are illogical and contradictory • Rules on compliance may change • Reinforces who is in control	***Enforcing trivial demands*** • Family members must stand apart • Masks in home and even when having sex • Random limits on people allowed to be together • Sanitizers to be used over and over in a day

www.beingfree.ca

The Chart of Coercion above is drawn from the Biderman Report on communist brainwashing techniques used by the Chinese and North Koreans on captured American servicemen to make them psychological as well as physical prisoners. Dr. Alfred D. Biderman M.A. and presented his Report at the New York Acadamy of Medicine Nov 13, 1956. Compare right column with your experience this year.

After a year of sustained psychological manipulation, the population is now weakened, frightened, desperate for a return of their freedoms, prosperity and normal lives, and especially vulnerable to pressure to take the Vaccine. The lockdowns and shutdowns, the myriad rules and regulations, the confusing and self-contradictory controls, the enforced docility, and the consequent demoralization, anxiety and helplessness are typical of authoritarian and totalitarian conditions. This degree of systemic and purposeful coercion means that Americans cannot give truly free and voluntary informed consent to the Vaccines.

At the same time, the population is being subjected to an aggressive, coordinated media campaign promoting the Vaccines funded by the federal government with $1 billion. The media campaign is reinforced by a system of coercive rewards and penalties designed to induce vaccination. The federal government is offering a range of its own incentives, including free childcare. The Ohio Governor rewarded those Ohio residents accepting the Vaccines by allowing them to enter into the "Vaxamillion" lottery with a total $5 million prize and the chance to win a fully funded college education, while barring entry for residents who decline the Vaccines. In New York, metro stations offer free passes to those receiving the Vaccine in the station. West Virginia is running a lottery exclusively for the vaccinated with free custom guns, trucks and lifetime hunting and fishing licenses, a free college education, and cash payments of $1.5 million and $600,000 as the prizes. Previously, the state offered a $100 savings bond for each injection with a Vaccine. New Mexican residents accepting the Vaccines will be entered into weekly drawings to take home a $250,000 prize, and those fully vaccinated by early August could win the grand prize of $5 million. In Oregon, the vaccinated can win $1 million, or one of 36 separate $10,000 prizes through the state's "Take Your Shot" campaign. Other state and local governments are partnering with fast food chains to offer free pizza, ice cream, hamburgers and other foods to the vaccinated. Many people are desperate following the last year of economic

destruction and deprivation of basic freedoms, and they are especially vulnerable to this coercion.

The penalties take many forms, among them:

- Using guilt and shame to make unvaccinated children and adults feel badly about themselves for refusing the Vaccines.

- Threatening the unvaccinated with false fears and anxieties about COVID-19, especially children who are at no risk statistically.

- Removing the rights of those who are unvaccinated, including:
  - Being prohibited from working
  - Being prohibited from attending school or college
  - Being limited in the ability to travel in buses, trains and planes
  - Being prohibited from traveling outside the United States
  - Being excluded from public and private events, such as performing arts venues.

Most recently, the President has announced an aggressive campaign to visit the homes of the unvaccinated, not for the purpose of ensuring that they have all of the information they might need in order to make fully informed, voluntary decisions about the Vaccines (the information required by § 360bbb–3(e)(1)(A)(i) and (ii)), but instead for the purpose of pressuring them to be injected with the Vaccine so that the Administration can reach its goal of having 70% of the American population vaccinated. He said: "Now we need to go to community by community, neighborhood by neighborhood, and oftentimes, door to door — literally knocking on doors — to get help to the remaining people protected from the virus."[20] The White House press secretary referred to the door-knockers who would enter our communities to pressure us to accept the Vaccines using the language of war, as "strike forces." Then, after Dr. Fauci stated his opinion in mainstream media news outlets that "at the local level . . . there should be more mandates,

[20] *See* "Biden admin launching door-to-door push to vaccinate Americans, sparks major backlash," https://www.foxnews.com/media/biden-admin-door-to-door-coronavirus-vaccines (last visited July 15, 2021).

there really should be", the press secretary announced that the Biden Administration would support state and local Vaccine mandates.[21]

A study recently published in the International Journal of Clinical Practice, "Informed Consent Disclosure to Vaccine Trial Subjects of Risk of COVID-19 Vaccines Worsening Clinical Disease,"[22] concludes:

> *COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the developmentand testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE).* ***This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.***

(emphasis added).

Plaintiffs' expert Dr. Lee Merritt is a fully licensed, board certified surgeon, and has been actively engaged in medical practice for over 35 years. As Chief of Staff, Chief of Surgery and Chief of Credentialing at a regional medical center, she participated in hospital administration and education with respect to *inter alia* informed consent. She states: "I have read the Complaint and Motion for Preliminary Injunction in the above captioned matter, specifically the allegations related to informed consent. I agree with the informed consent allegations contained in the Complaint and Motion for Preliminary Injunction" (*see* Declaration of Dr. Lee Merritt at Exhibit A). Dr. Merritt has provided an example of some of the language that she would recommend using for the purpose of obtaining voluntary, informed consent to the Vaccines.

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[21] *See* "Biden will back local vaccine mandates," https://thehill.com/changing-america/well-being/prevention-cures/562622-biden-will-back-local-vaccine-mandates (last visited July 15, 2021).
[22] *See* https://onlinelibrary.wiley.com/doi/epdf/10.1111/ijcp.13795 (last visited July 17, 2021).

The combined effect of (i) the suppression and censorship of information regarding the risks of the Vaccines, (ii) the failure to inform the public regarding the novel and experimental nature of the mRNA Vaccines, (iii) the suppression and censorship of information regarding alternative treatments, (iv) the failure to inform and properly educate the public that the Vaccines are not in fact "approved" by the FDA, (v) the failure to inform and properly educate the public that the DHHS Secretary has *not* determined that the Vaccines are "safe and effective" and on the contrary has merely determined that "it is reasonable to believe" that the Vaccines "may be effective" and that the benefits outweigh the risks, (vi) the sustained psychological manipulation of the public through official fear-based messaging regarding COVID-19, draconian countermeasures and a system of rewards and penalties, is to remove any possibility that Vaccine recipients are giving voluntary informed consent to the Vaccines. They have no real option to accept or refuse the Vaccines. They are unwitting, unwilling participants in a large scale, ongoing non-consensual human experiment.[23]

(7) § 360bbb–3(e)(1)(A)(iii): Monitoring and Reporting of Adverse Events

VAERS was established in 1986 in order to facilitate public access to information regarding adverse events potentially caused by vaccines. This system is inadequate to the present circumstances, for the following reasons:

- neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, that the DHHS Secretary "has authorized the emergency use of the [Vaccines]" since they are not being informed of the true meaning of the EUAs, specifically, that the Secretary has *not* determined that the Vaccines are "safe and effective" (notwithstanding the President's widely publicized statements to the contrary, which are amplified daily by countless other governmental and private sector statements that the Vaccines are "safe and effective"), and that instead the DHHS Secretary has only determined that he

[23] https://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States (last visited July 15, 2021).

has "reason to believe" that the Vaccines "may be effective" in treating or preventing SARS-CoV-2 and COVID-19, based on trials of the Vaccines that are not being conducted like any previous trials and are compressed, overlapping, incomplete and in many instances conducted by the Vaccine manufacturers themselves;

- neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of "the significant known and potential [ ] risks" of the Vaccines, since there is a coordinated campaign funded with $1 billion to extol the virtues of the Vaccines, and a simultaneous effort to censor information about the inefficacy of the Vaccines in preventing or treating SARS-CoV-2 and COVID-19, Vaccine risks, and injuries and deaths caused by the Vaccine;
- Vaccine recipients are not being informed by the Defendants, who have a financial stake in the intellectual property underlying at least one Vaccine, and who have other financial conflicts of interest, and conditions do not exist ensuring that others will inform them, that there are alternatives to the Vaccines and of their benefits;
- Vaccine recipients are not being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of their "option to accept or refuse" the Vaccines, since they have been saturated with unjustified fear-messaging regarding SARS-CoV-2 and COVID-19, psychologically manipulated, and coerced by a system of rewards and penalties that render the "option to [ ] refuse" meaningless; and
- Appropriate conditions do not exist for "the monitoring and reporting of adverse events" since only a fraction (as low as 1%) of adverse events are reported to VAERS by physicians fearing liability, and the Defendants have established a parallel reporting system for COVID-19 that is not accessible by Plaintiffs or the rest of the public.

A 2011 report by Harvard Pilgrim Healthcare for DHHS stated that fewer than 1% of all vaccine adverse events are reported to Defendants: "[F]ewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."[24]

To illustrate, while the CDC claims that "Anaphylaxis after COVID-19 vaccination is rare and occurred in approximately 2 to 5 people per million vaccinated in the United States

[24] Harvard Pilgrim Health Care, Inc., Electronic System for Public Health Vaccine Adverse Event Reporting System, *AHRQ* 2011.

based on events reported to VAERS,"[25] a recent study by Mass General Brigham found "severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations."[26] This is 50 to 120 times more cases than reported by VAERS and the CDC, meaning that only between 0.8% and 2% of all anaphylaxis cases are being reported by the Defendants. The underreporting is inexplicable, since it is mandatory for healthcare professionals to report this reaction to the Vaccines,[27] and the reactions typically occur within 30 minutes of vaccination.[28]

Uniquely for COVID-19, the CDC has developed a parallel system called "V-Safe." V-Safe is an app on a smart phone which people can use to report adverse events. Plaintiffs' investigation indicates that vaccine subjects who are provided with written information are given the V-Safe contact information. Plaintiffs cannot access V-Safe data, since it is controlled exclusively by the CDC. Plaintiffs are concerned that the information in V-Safe exceeds that in VAERS, in terms of volume and kind, defying Congressional intent in creating VAERS.

In summation, VAERS is inaccurate, and the federal government is failing to provide data from other sources such as V-Safe, Medicare/Medicaid, the military, etc. Informed consent cannot be given without an understanding of risk and Plaintiffs cannot help but wonder why the Defendants would fail to disclose this critical information related to risk to the public, particularly in light of the fact that they have had the time and resources to study and extend the authorizations on the Vaccines, build an enormous Vaccine marketing machine, and roll out Vaccine clinics all over the nation.

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[25] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.
[26] *See* https://jamanetwork.com/journals/jama/fullarticle/2777417.
[27] *See* https://www.fda.gov/media/144413/download.
[28] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

B. <u>The Under-18 Age Category</u>

In the United States, those younger than 18 years of age accounted for just 1.7% of all COVID-19 cases.[29] Essentially no severe cases of COVID-19 were observed in those aged 10 through 18 years. This group accounted for just 1% of reported cases, almost all of which were very mild.[30] A study recently published in the British Medical Journal concludes: "In contrast to other respiratory viruses, children have less severe symptoms when infected with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."[31] Hospitalization due to COVID-19 is incredibly rare among youth, and overstated. The American Academy of Pediatrics[32] reported:

> *…these studies underscore the importance of clearly distinguishing between children hospitalized with SARS-Co-V-2 found on universal testing versus those hospitalized for COVID-19 disease. Both demonstrate that reported hospitalization rates greatly overestimate the true burden of COVID-19 disease in children.*

Professor Hervé Seligmann, an infectious disease expert and biomedical researcher with over 100 peer-reviewed international publications, of the University of Aix-Marseille, has scrutinized the official COVID-19 statistics and figures of Israel, which has vaccinated 63% of its population, and fully vaccinated 57% of its population. Professor Seligmann sees no benefit in vaccinating those under 18, and significant risk of harm:

> *There are several theories about why the risk of death is so low in the young including that the density of the ACE2 receptors that the virus uses to gain entry into cells is lower in the tissue of immature animals and this is expected to be true also in humans. However, the vaccines induce the cells of the recipient to*

[29] Coronavirus Disease 2019 in Children - United States, February 12-April 2, 2020. *MMWR. Morbidity and Mortality Weekly Report* 69:422-426.

[30] Tsabouri, S. et al. (2021), Risk Factors for Severity in Children with Coronavirus Disease 2019: A Comprehensive Literature Review. *Pediatric Clinics of North America* 68:321-338.

[31] Zimmermann P, Curtis N Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections Archives of Disease in Childhood 2021;106**:**429-439.

[32] Ioannidis, J.P.A. (2020) Infection fatality rate of COVID-19 inferred from seroprevalence data. Bull. World Health Organ. -:BLT.20.265892.

> *manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, strong immune responses, including those which can damage their own cells and tissues as well as by stimulating blood coagulation. Experts predict that vaccination will greatly increase the very low COVID-19 risks experienced by the younger population … vaccination-associated mortality risks are expected at least 20 times greater below age 20 compared to the very low COVID19-associated risks for this age group.*[33]

CDC data indicates that children under 18 have a 99.998% COVID-19 recovery rate with no treatment. This contrasts with over 45,000 deaths (*see* below) and hundreds of thousands of adverse events reported following injection with the Vaccines. The risk of harm to children may be as high as 50 to 1. Thus, children under 18 are at no statistically significant risk of harm from SARS-CoV-2 and COVID-19. Administering Vaccines to this age group knowingly and intentionally exposes them to unnecessary and unacceptable risks.

Plaintiffs' expert Dr. Angelina Farella is a fully licensed, board certified pediatrician, actively practicing for over 25 years, and has vaccinated in excess of 10,000 patients (see Declaration of Angelina Farella, MD at Exhibit B). Dr. Farella states, in her professional medical opinion: "There are 104 children age 0-17 who have died from Covid-19 and 287 from Covid + Influenza out of roughly 72 million children in America. This equals ZERO risk. There is NO public interest in subjecting children to experimental vaccination programs, to protect them from a disease that does not threaten them." Dr. Farella also opines, with respect to the lack of testing designed to ensure the safety of this subpopulation:

> *Vaccines take years to safely test. It's not only the number of people tested but the length of time that is important when creating new vaccines. Emergency Use Authorization was granted prematurely for adolescents, before ANY trials were completed. Moderna is scheduled to complete trials on October 31, 2022, and Pfizer is scheduled to complete trials on April 27, 2023. There were no trial*

[33] Seligmann, H., (2021), Expert Evaluation on Adverse Effects of the Pfizer COVID-19 Vaccination. *See* https://www.researchgate.net/publication/351441506_Expert_evaluation_on_adverse_effects_of_the_Pfizer-COVID-19_vaccination (last visited July 8, 2021).

> *patients under the age of 18. The FDA and these pharma companies are currently allowing children 12 years old to receive this shot, when they were never studied in the trials.* ***Never before in history have we given medications that were not FDA approved to people who were not initially studied in the trial.***

Section 360bbb–3(c)(2) requires the Secretary to base decisions on "data from adequate and well-controlled clinical trials". Clearly, the Secretary has exceeded his statutory authority with respect to the under-18 subpopulation.

Meanwhile, local governments are hastily passing laws eliminating the requirement for parental consent, and even parental knowledge, of medical treatments administered to children as young as 12. This is intended to pave the way for children to be vaccinated at school, without parental knowledge or consent.

Children in the 12-18 age group are not developmentally capable of giving voluntary, informed consent to the Vaccines. Their brains are rapidly changing and developing, and their actions are guided more by the emotional and reactive amygdala and less by the thoughtful, logical frontal cortex. Hormonal and body changes add to their emotional instability and erratic judgment. Children also have a well-known and scientifically studied vulnerability to pressure from peers and adults. This age group is particularly susceptible to pressure to do what others see as the right thing to do — in this case, to be injected with the Vaccine "for the sake of other people and society."

Injecting this under-18 subpopulation with the Vaccines threatens them with immediate, potentially life-threatening harm. The documented risks of injecting this subpopulation with the Vaccines far outweigh the purported benefits.

C. Those Previously Infected with SARS-CoV-2

Medical studies show that those with preexisting immunity have long lasting and robust natural immunity to SARS-CoV-2.[34] A recent Cleveland Clinic study[35] demonstrates that natural immunity acquired through prior infection with COVID-19 is stronger than any benefit conferred by a Vaccine, rendering vaccination unnecessary for those previously infected. A comparative study by Goldberg *et al* "questioned the need to vaccinate previously-infected individuals" and noted that previously infected individuals had 96.4% immune protection from COVID-19, versus 94.4% in those injected with the Vaccine.[36]

The Israeli Ministry of Health has released data showing that Israelis who had been previously infected with SARS-CoV-2 (and were not also vaccinated) were far less likely to become re-infected with the virus than those in the population who had been injected with the Vaccines.[37] Of the more then 7,700 new cases detected during the recent wave that commenced in May 2021, only 72, or less than 1%, were people who had previously been infected with SARS-CoV-2 and were never vaccinated. By contrast, over 3,000 cases, or 40%, were people who became infected for the first time, in spite of being vaccinated. The 72 instances of re-infection represent a mere 0.0086% of the 835,792 Israelis who are known to have recovered from the virus.

The immutable laws of immunology continue to function during COVID-19 (meaning those who are previously recovered from such an infection have acquired the ability to recognize disease and can effectively neutralize the infection before it takes hold), as evidenced by the fact

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[34] *See* https://www.nature.com/articles/d41586-021-01442-9, and https://www.thelancet.com/journals/lancet /article/PIIS0140-6736(21)00782-0/fulltext (last visited July 14, 2021).
[35] Shrestha, N., Burke, P., Nowacki, A., Terpeluk, P., Gordon, S. (2021), Necessity of COVID-19 Vaccination in Previously Infected Individuals. See https://www.medrxiv.org/content/ 10.1101/2021.06.01.21258176v2 (last visited July 8, 2021).
[36] *See* https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full.pdf (last visited July 13, 2021).
[37] *See* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited July 15, 2021).

that persons who have had SARS-CoV-1, a virus which is 22% dissimilar to the current strain, are still immune from SARS-CoV-2 18 years later.[38] Laypersons are misled to believe that when antibodies gradually diminish as expected, immunity is gone when in fact, immunity remains[39] quiescent deeper in the body, in the bone marrow[40], plasma, ready to be activated should the threat reemerge. This is normal immunology.

Not only is a Vaccine unnecessary in this subpopulation, it is more likely to cause harm. Scientists have observed vaccine-driven disease enhancement in the previously infected. The FDA admits that many people receiving a Vaccine either are or were previously infected with SARS-CoV-2, or have or previously had COVID-19.[41] Upon injection with the Vaccines, this population has reported serious medical harm, including death.[42] There is an immediately higher death rate worldwide upon receiving a Vaccine, generally attributed to persons having recently been infected with COVID-19. A person who previously had SARS-CoV-2, and then receives a Vaccine, mounts an antibody response to the Vaccine that is between 10 and 20 times stronger than the response of a previously uninfected person. The antibody response is far too strong and overwhelms the Vaccine subject. Medical studies show severe Vaccine side effects in persons previously infected with COVID-19.[43] A study published in the New England Journal of Medicine noted antibody titers 10-45 times higher in those with preexisting COVID-19 immunity after the first Vaccine injection, **with 89% of those seropositive reporting adverse side-effects.**[44] This substantial risk is suppressed in mainstream national news. Groups of scientists are demanding improved pre-assessment due to "Vaccine-driven disease enhancement"

[38] See https://www.nature.com/articles/s41586-020-2550-z (last visited July 14, 2021).
[39] https://www.medpagetoday.com/infectiousdisease/covid19/92836 (last visited July 14, 2021).
[40] https://www.nature.com/articles/s41586-021-03647-4 (last visited July 14, 2021).
[41] *See* https://www.fda.gov/media/144245/download (last visited July 13, 2021).
[42] *See* https://www.bridgemi.com/michigan-health-watch/three-michigan-people-who-died-after-vaccine-actually-had-earlier-covid; https://www.bmj.com/content/bmj/373/bmj.n1372.full.pdf (last visited July 13, 2021).
[43] See https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1.full.pdf (last visited July 13, 2021).
[44] See https://www.nejm.org/doi/10.1056/NEJMc2101667 (last visited July 13, 2021).

in the previously infected, a subpopulation which has been excluded from clinical trials. The failure to protect a subpopulation at higher risk, such as this one, is unprecedented. Injecting this subpopulation with the Vaccines, without prescreening, threatens them with immediate, potentially life-threatening harm.

Plaintiffs' expert Dr. Richard Urso is a fully licensed, board certified, practicing medical doctor (see Declaration of Dr. Richard Urso at Exhibit C). Dr. Urso has treated over 300,000 patients in his career, including over 450 COVID-19 recovered patients. In his professional medical opinion:

> *COVID recovered patients are at extremely high risk to a vaccine. They retain an antigenic fingerprint of natural infection in their tissues. They have all the requisite components of immune memory. Vaccination may activate a hyperimmune response leading to a significant tissue injury and possibly death.*
>
> *I have read the Complaint and Motion for Preliminary Injunction in the above captioned matter, specifically the allegations related to the dangers to members of the population who have already had Covid-19. I agree with the allegations contained in the Complaint and Motion for Preliminary Injunction.*

Pre-screening can be accomplished in the traditional way by (1) obtaining relevant personal and family medical history including prior COVID-19 symptoms and test results, (2) obtaining antibody and T-Detect testing from indeterminate persons, (3) obtaining rapid PCR screening testing on all persons (using at least the standard cycle thresholds set forth *infra*). If the prescreening results are positive, the Vaccine candidate must be excluded. The documented risks of indiscriminately injecting this subpopulation with the experimental Vaccines far outweigh the purported benefits.

For additional support of the foregoing sections, and this Motion for Injunctive Relief generally, please see the duly sworn Declaration of Dr. Peter A. McCullough, attached hereto and incorporated herein with reference to Exhibit L.

D. Whistleblower Testimony: 45,000 Deaths Caused by the Vaccines

Plaintiffs' expert Jane Doe[45] is a computer programmer with subject matter expertise in the healthcare data analytics field, and access to Medicare and Medicaid data maintained by the Centers for Medicare and Medicaid Services (CMS) (*see* Declaration of Jane Doe at Exhibit D). Over the last 20 years, she has developed over 100 distinct healthcare fraud detection algorithms for use in the public and private sectors. In her expert opinion, VAERS under-reports deaths caused by the Vaccines by a conservative factor of at least 5. As of July 9, 2021, VAERS reported 9,048 deaths associated with the Vaccines. Jane Doe queried data from CMS medical claims, and has determined that the number of deaths occurring with 3 days of injection with the Vaccines exceeds those reported by VAERS by a factor of at least 5, indicating that **the true number of deaths caused by the Vaccines is at least 45,000.** She notes that in the 1976 Swine Flu vaccine campaign (in which 25% of the U.S. population at that time, 55 million Americans, were vaccinated), the Swine Flu vaccine was deemed dangerous and unsafe, and removed from the market, even though the vaccine resulted in only 53 deaths.

The gross and willful under-reporting of Vaccine-caused deaths, which is substantiated by Jane Doe's Declaration, and also by other independent data points considered as part of Plaintiffs' due diligence, is profoundly important on a number of levels. This evidence increases the likelihood of Plaintiffs' success on the merits by: (1) making it impossible (a) that the DHHS Secretary can reasonably conclude, as required by § 360bbb–3(c)(2)(B), that "the known and potential benefits of [the Vaccines] outweigh the known and potential risks of [the Vaccines]",

[45] Plaintiffs' expert Jane Doe is a whistleblower who fears for her personal safety and that of her family, and reprisal, including termination and exclusion from her chosen profession for the duration of her working life, for disclosing the evidence contained in her Declaration at Ex. D. Plaintiffs will present the Court with a motion for an appropriately tailored protective order seeking to preserve the confidentiality of Jane Doe's identity. In the meantime, Defendants are not prejudiced, since they can respond to the substance of Jane Doe's Declaration and challenge her expert qualification without knowing her true identity. Plaintiffs' counsel have in their possession a copy of this same Declaration of Jane Doe, signed by the witness in her actual name.

(b) that the DHHS Secretary has succeeded in creating conditions, as required by § 360bbb–3(e)(1)(A)(i)(II) and (ii)(II), that ensure that healthcare professionals and Vaccine candidates are informed of the "significant known and potential [ ] risks" of the Vaccines, and (c) that the DHHS Secretary has succeeded in creating conditions, as required by § 360bbb–3(e)(1)(A)(iii), for the monitoring and reporting of adverse events; and (2) sealing Plaintiffs' argument that the FDA's "citizen petition" process (discussed *infra* in section III(1)) is "inadequate and not efficacious" and that its pursuit by Plaintiffs would have been a "futile gesture" by showing Defendants' bad faith. The evidence makes it irrefutable that Plaintiffs and others in the public will suffer irreparable injury (discussed *infra* in section III(2)) if this Motion is denied. Finally, the evidence tilts the balance of hardships and public interest (discussed *infra* in Section III(3) decisively in favor of Plaintiffs.

III. LAW AND ANALYSIS

In the 11th Circuit, a district court may grant preliminary injunctive relief when:

> *"a party establishes each of four separate requirements: (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest."*

Jones v. Governor of Fla., 950 F.3d 795, 806 (11th Cir. 2020). However, the court has "considerable discretion…in determining whether the facts of a situation require it to issue an injunction." eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (internal quotations and citations omitted).

A. Likelihood of Success on the Merits

As a threshold matter, parties seeking a preliminary injunction "are not required to prove their claim, but only to show that they [are] likely to succeed on the merits." Glossip v. Gross, 135 S. Ct. 2726, 2792 (2015); Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008).

While the burden of persuasion remains with the Plaintiffs, the "burdens at the preliminary injunction stage track the burdens at trial." Gonzales v. O Centro Espírita Beneficente Uniã do Vegetal, 546 U.S. 418, 428–30 (2006). For the purposes of a preliminary injunction, this burden of proof can be shifted to the party opposing the injunctive relief after a *prima facie* showing, and the movant should be deemed likely to prevail if the non-movant fails to make an adequate showing. Id.

(1) Plaintiffs Have Standing

Plaintiffs have standing to assert these claims. They have demonstrated that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that it is likely to be redressed by a favorable decision." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992).

Plaintiffs have alleged specific physical injuries caused by the Vaccines, death caused by the Vaccines, actual and threatened loss of employment, and violations of their constitutionally protected rights to personal autonomy, bodily integrity, and to work in a profession of their choosing, each of which constitutes "an invasion of a legally protected interest" that is "concrete," "particularized," and "actual or imminent, not conjectural or hypothetical" as required under Spokeo, Inc. v. Robins, 136 S.Ct. 1540, 1548 (2016). Their pleadings are supported by Declarations made under oath.

The participation of third parties in the chain of causation does not defeat Plaintiffs' claims or their standing, since their injuries are "fairly traceable" to the Defendants. *See* Simon

v. Eastern Kentucky Welfare Rights Org., 426 U.S. 26, 45 n.25 (1976) (noting cases providing that privately inflicted injury is traceable to government action if the injurious conduct "would have been illegal without that action"); National Wildlife Federation v. Hodel, 839 F.2d 694, 705 (D.C. Cir. 1988) ("The Supreme Court's decisions on this point show that mere indirectness of causation is no barrier to standing, and thus, an injury worked on one party by another through a third party intermediary may suffice."); Telephone and Data Systems, Inc. v. FCC, 19 F.3d 42, 47 (D.C. Cir. 1994) ("injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality" . . . "the relief sought would constitute a 'necessary first step on a path that could ultimately lead to relief fully redressing the injury'" . . . "the relief requested 'will produce tangible, meaningful results in the real world.'"); Motor & Equip. Mfrs. Ass'n v. Nichols, 142 F.3d 449, 457-58 (D.C. Cir. 1998) (petitioner had standing to challenge government action based on the independent conduct of third parties where evidence demonstrated that the challenged action "resulted in an almost unanimous decision" by those third parties to take action that harmed the petitioner); America's Community Bankers v. FDIC, 200 F.3d 822, 827-28 (D.C. Cir. 2000) ("an agency does not have to be the direct actor in the injurious conduct, but that indirect causation through authorization is sufficient to fulfill the causation requirement for Article III standing."); Consumer Federation of America v. F.C.C., 348 F.3d 1009, 1012 (D.C. Cir. 2003) ("When an agency order permits a third-party to engage in conduct that allegedly injures a person, the person has satisfied the causation aspect of the standing analysis.").

A favorable decision of this Court will likely redress Plaintiffs' injuries. The Vaccine-injured Plaintiffs continue to suffer the adverse effects of the Defendants' wrongdoing, and their physical injuries are still unfolding. Their personal injuries can be redressed in the usual way, by

an award of civil money damages for pain and suffering, emotional distress, economic loss and medical monitoring.

(2) Defendants' Actions are Reviewable

Plaintiffs have alleged that there is no real emergency as required by § 360bbb–3(b), that Defendants have willfully failed to satisfy the statutory criteria for issuing the Vaccine EUAs required by § 360bbb–3(c), and that Defendants have failed to create and maintain the conditions of authorization for the Vaccine EUAs required by § 360bbb–3(e) (Counts I, II, III and VI).

The Administrative Procedures Act ("APA") imposes four requirements that must be met before a federal court can review agency action: (1) the alleged injury must "arguably" be within the "zone of interests" protected or regulated by the statute in question, (2) no statute precludes judicial review, (3) the agency action is "final" and (4) the agency action is not "committed to agency discretion" by law.

i. Plaintiffs' Injuries are Within the Zone of Interests

The "zone of interests" test is "*not* 'especially demanding'" Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 130 (2014) (quoting Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak, 567 U.S. 209, 225 (2012)). The Supreme Court has "conspicuously included the word 'arguably' in the test to indicate that the benefit of any doubt goes to the plaintiff. " Id. The test "'forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that' Congress authorized that plaintiff sue." Collins v. Mnuchin, 938 F.3d 553, 574 (5th Cir. 2019) (quoting Lexmark, 572 U.S. at 130.). The Vaccine injuries and death, and the violations of the constitutionally protected right to bodily integrity and personal autonomy that Plaintiffs assert in the Complaint, are within the zone of interests protected by these statutory provisions, the purpose of which is to tightly limit the circumstances in which

potentially harmful medical products can be placed in the stream of commerce and used by the American public prior to their full approval by the FDA.

ii. No Statutory Preclusion

Plaintiffs can locate no valid statute purporting to preclude judicial review of this agency action, either categorically, or prior to the exhaustion of administrative remedies.

Defendants may cite to 42 U.S.C. § 247d-6d(b)(7), a provision of the Public Readiness and Emergency Preparedness Act ("PREP Act"), which states: "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." However, a "strong presumption in favor of judicial review of administrative action" governs the construction of potentially jurisdiction-stripping provisions like § 247d-6d(b)(7). INS v. St. Cyr, 533 U.S. 289, 298 (2001). "Even when the ultimate result is to limit judicial review, the Court cautions that as a matter of the interpretive enterprise itself, the narrower construction of a jurisdiction-stripping provision is favored over the broader one." ANA Inti'l Inc. v. Way, 393 F.3d 886, 891 (2004) (citing to Reno v. American-Arab Anti-Discrimination Committee, 525 U.S. 471, 480-482 (1999)); see also Patel v. United States AG, 917 F.3d 1319, Fn. 4 (11th Cir. 2019) ("We are also mindful that there is a strong presumption in favor of interpreting statutes to allow judicial review of administrative actions; consequently, jurisdiction stripping is construed narrowly."), (citing to Kucana v. Holder, 558 U.S. 233, 251-252 (2010).

Thus the prohibition on judicial review in § 247d-6d(b)(7) must be construed narrowly so as to apply exclusively and specifically to declarations conferring the PREP Act "immunity" described in § 247d-6d(a), which are the only declarations made by the Secretary under "this subsection." Section 247d-6d(b)(1) refers to the Secretary's having first and beforehand made a declaration that a public health emergency exists (a declaration that is made under an entirely

different statute, 21 U.S.C. § 360bbb–3(b)), and states that if such a public health emergency declaration has been made, then the Secretary may confer PREP Act immunity by publishing a notice of same in the Federal Register.

Any broader interpretation of § 247d-6d(b)(7) — and in particular, any broader interpretation that purports to categorically eliminate judicial review of actions taken under § 360bbb–3 — is an unconstitutional delegation of legislative power by Congress to the executive branch. It is unconstitutional for three reasons. First, it is unconstitutional because it is devoid of any "'intelligible principle' on which to judge the conformity of agency action to the congressional grant of power." Florida v. Becerra, 2021 U.S. Dist. LEXIS 114297 (M.D. Fl. 2021) (quoting J.W. Hampton, Jr., & Co. v. Unitd States, 276 U.S. 394, 409 (1928)). Further, it purports to categorically exclude, rather than merely limiting, all judicial review. Finally, it is unconstitutional because it purports to eliminate judicial review in that most constitutionally perilous of situations, a state of emergency unilaterally declared and sustained by an executive branch official.

In Home Building and Loan Association v. Blaisdell, 290 U.S. 398 (1934), the U.S. Supreme Court stated: "Whether an emergency exists upon which the continued operation of the law depends is always open to judicial inquiry." 290 U.S. at 442, citing Chastleton Corp. v. Sinclair, 264 U.S. 543 (1924). In Sinclair, the Supreme Court stated: "A law depending upon the existence of emergency or other certain state of facts to uphold it may cease to operate if the emergency ceases or the facts change." 264 U.S. at 547. Both Blaisdell and Sinclair are clear authority that an emergency and the rules promulgated thereunder must end when the facts of the situation no longer support the continuation of the emergency. They also forbid this Court to merely assume the existence of a "public health crisis" based on the pronouncements of the Executive Defendants. They are clear authority that it is the duty of the court of first instance to

grapple with this question and conduct an inquiry. "[A] Court is not at liberty to shut its eyes to an obvious mistake when the validity of the law depends upon the truth of what is declared." Id. The Sinclair court instructed lower court's to inquire into the factual predicate underlying a declaration of emergency, where there appears to have been a change of circumstances: "the facts should be gathered and weighed by the court of first instance and the evidence preserved for consideration by this Court if necessary." 264 U.S. at 549.

In Sterling v. Constantin. 287 U.S. 378 (1932), the Supreme Court reviewed the actions of the Texas Governor in declaring martial law and interfering with oil well production in a manner that impaired private drilling rights. In holding that the question whether an emergency existed justifying such interference with the plaintiffs' property rights was subject to judicial inquiry and determination, the Court stated:

> *If this extreme position could be deemed to be well taken, it is manifest that the fiat of a state governor, and not the Constitution of the United States, would be the supreme law of the land; that the restrictions of the federal Constitution upon the exercise of state power would be but impotent phrases, the futility of which the state may at any time disclose by the simple process of transferring powers of legislation to the Governor to be exercised by him, beyond control, upon his assertion of necessity. Under our system of government, such a conclusion is obviously untenable. There is no such avenue of escape from the paramount authority of the federal Constitution. When there is a substantial showing that the exertion of state power has overridden private rights secured by that Constitution, the subject is necessarily one for judicial inquiry in an appropriate proceeding directed against the individuals charged with the transgression.*

287 U.S. at 397-98.

Similarly, the actions of the Secretary must be subject to judicial review. Under 21 U.S.C. § 355(q)(1)(A), the DHHS Secretary

> *shall not delay approval of a pending application [ ] because of any request to take any form of action relating to the application, either before or during consideration of the request, unless — (i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations . . .*

21 C.F.R. § 10.30 in turn provides for so called "citizen petitions" which are a form of administrative redress. However, a close reading of the statutory language and due consideration of the underlying policies compel the conclusion that Congress did not intend to preclude judicial review of this particular agency action.

Section 355(q) could easily state that interested parties "shall not pursue" (or the equivalent) lawsuits prior to the completion of the citizen petition process. It does not. Instead, the only mandatory language in § 355(q) is directed at the Secretary, not at citizens, and it states that the Secretary "shall not delay". This language is intended to target the predominant, anti-competitive mischief marring the FDA approval process at the time the statute was enacted. Entrenched market participants abused the citizen petition process by soliciting citizenry to file petitions for the improper purpose of delaying applications for new drug approval submitted by new market entrants.[46] Senator Edward Kennedy explained: "The citizen petition provision is designed to address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health."[47] The statutory language should be read narrowly in accordance with that purpose, to apply only to the "approval of a pending application" which should not be delayed.

Plaintiffs here are seeking first and foremost the **revocation** or **termination** of the declared emergency and existing Vaccine EUAs, and not for anti-competitive purposes, but in order to respond to unlawful agency action driven by financial conflicts of interest, political pressure and fear, the substantial risk of widespread personal injury and death, and constitutional infractions.

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[46] See *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 252 (2012) ("The study finds that brand drug companies file 68% of petitions, far more than generic firms or other parties such as universities, doctors or hospitals. Of the petitions by brand firms, more than 75% target generic entrants.").

[47] 153 Cong. Rec. 25,047 (2007).

Further, neither 21 U.S.C. § 355 nor 21 C.F.R. § 10.30 expressly references § 360bbb–3, the statute pursuant to which the emergency has been declared and the Vaccines released to the public. Conversely, § 360bbb–3 does not expressly refer to 21 U.S.C. § 355 nor 21 C.F.R. § 10.30. If Congress had intended for the citizen petition process — designed to address the specific mischief of anti-competitive behavior — to apply to the very particular and very different circumstances of an emergency use authorization of highly experimental and potentially dangerous medical interventions with the potential to rapidly injure or kill large swathes of the American populace, surely it would have said so. Plaintiffs are the current and future Vaccine-injured in a time of purported emergency, complaining of gross agency malfeasance and conflicts of interest, not profit-seeking market participants.

Neither should the judicial doctrine of "exhaustion of administrative remedies" bar judicial review. "[J]udicially created exhaustion requirements are 'subject to numerous exceptions.'" <u>Georgia v. United States</u>, 398 F.Supp. 1330, 1343 (S.D. Ga. 2019) (quoting <u>Kentucky v. United States ex rel. Hagel</u>, 759 F.3d 588, 599 (6th Cir. 2014)). In their discretion, the district courts

> *"…have recognized at least three prudential exceptions to exhaustion requirements. [ ] Exhaustion may be excused if a litigant can show: (1) that requiring exhaustion will result in irreparable harm; (2) that the administrative remedy is wholly inadequate; or (3) that the administrative body is biased, making recourse to the agency futile."*

<u>Id</u>. (quoting <u>Kansas Dept. for Children and Families v. SourceAmerica</u>, 874 F.3d 1226, 1250 (10th Cir. 2017) ("We permit district courts to excuse a failure to exhaust where '(1) the plaintiff asserts a colorable constitutional claim that is collateral to the substantive issues of the administrative proceedings, (2) exhaustion would result in irreparable harm, and (3) exhaustion would be futile.'")).

Courts have recognized exceptions to the requirement of administrative exhaustion in the specific context of the FDCA and 21 C.F.R. § 10.30. *See, e.g.*, Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1378 (9th Cir. 1983) ("Biotics and Seroyal admit failing to take advantage of this available administrative remedy, but argue that the administrative remedy is 'inadequate and not efficacious' and that its pursuit would have been a 'futile gesture.' **Although we recognize an exception to the exhaustion requirement in these circumstances**, there is nothing in the record to indicate that a citizens petition to the Commissioner would have been ineffective or futile." (emphasis added)) (citing to AMP Inc. v. Gardiner, 275 F.Supp. 410 (S.D.N.Y. 1967), aff'd, 389 F.2d 825 (2d Cir. 1968), cert. denied, 393 U.S. 825 (1968); Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 801 (2d Cir. 1980), Natick Paperboard Corp. v. Weinberger, 498 F.2d 125, 128-29 (1st Cir. 1974).

The record in this case contains abundant evidence that the citizen petition process is both "inadequate and not efficacious". First and most importantly, the FDA need not respond to a citizen petition for 5 months, and in fact as a practical matter the "deadline" is more honored in the breach than the observance. When the FDA does respond, its response may be indeterminate. The chart below constructed from VAERS data shows that the American public cannot afford to wait for 5 months, while physical injuries and deaths due to the Vaccine skyrocket. Jane Doe's expert testimony that the true number of deaths caused by the Vaccine is in excess of 45,000 (*see* Declaration at Ex. D) renders the Defendants' likely argument that Plaintiffs must muddle through the citizen petition process before bringing this litigation not just legally absurd, but inhumane.

VAERS DATA		
APRIL 23, 2021	**JULY 2, 2021**	**% INCREASE**
118,902 ADVERSE EVENTS	438,441 ADVERSE EVENTS	72.88%
3,544 DEATHS	9,048 DEATHS	60.83%
12,619 INJURIES	41,015 INJURIES	69.23%

Plaintiff AFLDS' experience with the citizen petition process to date substantiates the argument. The Complaint alleges that Defendants are suppressing information regarding the availability of safe and effective alternative prophylaxis and treatments for COVID-19, including for example hydroxychloroquine (ECF 10, ¶¶ 219-228). Plaintiff AFLDS filed a citizen petition regarding hydroxychloroquine on October 12, 2020, requesting that the FDA exempt hydroxychloroquine-based drugs from prescription-dispensing requirements and make them available to the public over-the counter (*see* Citizen Petition at Exhibit E). The FDA acknowledged receipt of the petition on October 13, 2020. (*see* FDA Acknowledgment Letter at Exhibit F). Then on April 8, 2021, the FDA wrote to AFLDS to say that it "has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." (*see* FDA Delay Letter at Exhibit G). As recently as June 21, 2021 the FDA has confirmed by email that it has no substantive response to the Citizen's Petition, responding to AFLDS' request for an update by referring back to the FDA's April 8 delay letter! The issues raised in the Complaint and in this Motion would almost certainly be claimed to be equally or more complex, and there is no reason whatsoever to believe that the FDA will respond substantively to them within the statutory deadline, or in any amount of time shorter than the 10 months that have passed since the hydroxychloroquine petition was filed. All of this is becomes

even more relevant in light of the fact that while a response to a citizen's petition is put off for many months, the vaccines were approved with no delay.

Not only is the citizen petition process fatally slow, the FDA is ultimately powerless to award civil money damages for the physical injury and death that have invaded Plaintiffs' constitutional right to personal autonomy and bodily integrity. These are irreparable injuries. Winck v. England, 327 F.3d 1296, 1304 (11th Cir. 2003) ((“[exhaustion] is not required where no genuine opportunity for adequate relief exists, **irreparable injury** will result if the complaining party is compelled to pursue administrative remedies, or an administrative appeal would be futile”) (emphasis added)).

The pursuit of a citizen petition is also a “futile gesture” since the FDA will not grant the relief requested by Plaintiffs. An empirical study has shown that the mean and median citizen petition grant rates fluctuated between 0% and 16% in the eight years from 2003 through 2010, and the mean and median denial rates were both 92%.[48] The real and substantial financial conflicts of interest compromising the Defendants and their key officials involved in the § 360bbb–3 process (*see* Complaint, ECF 10, ¶¶ 250-256), combined with the immense pressure[49] placed on the FDA by industry and politicians to fast track the approval process, and Jane Doe's revelation that the Defendants have intentionally concealed from the public that the true number of deaths caused by the Vaccines is at least 45,000 not the approximately 9,000 reported by VAERS (*see* Declaration at Ex. D), destroy any pretense that the FDA could adjudicate such a citizen petition with fairness and impartiality.

The policy justification traditionally cited by those courts that have required compliance with the citizen petition process do not apply here. *See, e.g.*, Garlic v. United States Food &

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[48] *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. at 275.

[49] Gardner, L., “Calls Mount on FDA to Formally Endorse COVID Vaccines as Delta Surges” (July 8, 2021). *See* https://news.yahoo.com/calls-mount-fda-formally-endorse-182622109.html (last visited July 12, 2021).

Drug Administration, 783 F.Supp. 4, 5 (D. D.C. 1992) ("Allowing 'interested parties' to bypass the administrative remedies would undermine the entire regulatory process. Drug manufacturers could circumvent the FDA's procedures by soliciting private citizens to sue for judicial approval new medications."). Plaintiffs are not attempting to circumvent the substantive provisions of § 360bbb–3 in order to force the approval and release of a new experimental drug, rather they are trying to force the FDA, its officials riddled with serious conflicts of interests, to comply with these provisions in order prevent widespread personal injury and death and egregious violations of the constitutionally protected rights to personal autonomy and bodily integrity.

Count VI of the Complaint seeks mandamus, since there is "'practically no other remedy.'" Collin v. Berryhill, 2017 U.S. Dist. LEXIS 78222 at *9 (quoting Helstoski v. Meanor, 442 U.S. 500, 505 (1979). Courts have held that the perceived medical urgencies created by COVID-19 itself, and also those created by the decisions, orders and actions of authorities responding to COVID-19, can make it impractical and inappropriate to force a plaintiff seeking *mandamus* to wait for alternative processes to run their course:

> *Moreover, given the broader context of the COVID-19 pandemic, we agree with the Fifth Circuit that "[i]n mill-run cases, it might be a sufficient remedy to simply wait for the expiration of the TRO, and then appeal an adverse preliminary injunction. In other cases, a surety bond may ensure that a party wrongfully enjoined can be compensated for any injury caused. Those methods would be woefully inadequate here."*

In re Rutledge, 956 F.3d 1018, 1026 (8th Cir. 2020), quoting In re Abbott, 2020 U.S. App. LEXIS 10893 at *14.[50]

[50] The Supreme Court subsequently vacated the judgment in In re Abbott, and remanded to the Fifth Circuit with instructions to dismiss the case as moot, following the Texas Governor's relaxation of his order restricting abortion as a non-essential surgical procedure, however the decision did not turn on an analysis of mandamus. *See*, Planned Parenthood Ctr. for Choice v. Abbott, 2021 U.S. LEXIS 647.

iii. The Emergency Declaration and the EUAs are "Final" Agency Action

In order to be deemed "final", an agency action (1) "must mark the consummation of the agency's decision-making process — it must not be of a merely tentative or interlocutory nature" and (2) "must be one by which rights or obligations have been determined, or from which legal consequences will flow." United States Corps of Eng'rs v. Hawkes Co., 136 S.Ct. 1807, 1813 (2016) (quoting Bennett v. Spear, 520 U.S. 154, 177-178 (1997)).

After fact-finding and consultation, the DHHS Secretary declared, under § 360bbb–3(b), that there is an emergency. Once issued, his declaration remained valid for a period of time and was serially renewed. The declaration is not merely "advisory in nature." Id. It represents the "consummation of the decision-making process" with respect to whether or not an emergency exists. The declaration also gives rise to "'direct and appreciable legal consequences.'" Id. at 1814. The declaration paved the way for Pfizer, Moderna and Janssen to apply for EUAs for their experimental Vaccines, for the DHHS Secretary and his designee the FDA Commissioner to adjudicate and approve their EUA applications, and for the Vaccines to be released into interstate commerce and injected into millions of Americans.

The FDA Commissioner engaged in fact-finding and made vital determinations that the statutory criteria for issuing the Vaccine EUAs required by § 360bbb–3(c) were met, and that the conditions of authorization for the Vaccine EUAs required by § 360bbb–3(e) were also met. On that basis, the Vaccine EUAs were issued. The issuance of the Vaccine EUAs represents the "consummation of the decision-making process" with respect to whether or not EUAs will be granted, and also gave rise to "'direct and appreciable legal consequences'" since millions of people have been injected with these experimental Vaccines while their manufacturers have made billions of dollars in revenues under an immunity shield.

iv. Not "Committed to Agency Discretion"

The emergency declaration is not committed to agency discretion by law. Section 360bbb–3(b)(1) states that the DHHS Secretary "may" make a declaration, but then proceeds to enumerate in detail the limited bases upon which the declaration may be made, at least three of which prohibit unilateral declarations by the Secretary by requiring consultation with or the prior decisions of other cabinet-level executive branch officials. Section 360bbb–3(b)(3) prohibits the Secretary from unilaterally terminating the declaration. This is not a broad grant of discretion, but even if it were, "[t]he fact that a statute grants broad discretion to an agency does not render the agency's decisions completely unreviewable unless the statutory scheme, taken together with other relevant materials, provides absolutely no guidance to how that discretion is to be exercised." Louisiana v. Biden, 2021 U.S. Dist. LEXIS 112316 * 40-41 (W. D. La. 2021).

Section 360bbb–3(b)(1)(c) is the sole ground for an emergency that does not seem to require consultation with or the prior decisions of other cabinet-level executive branch officials, and it provides guidance to the Secretary by requiring him to make a 4-pronged finding that (parsing the statute): (i) there is a "public health emergency" (ii) that "affects, or has a significant potential to affect" (iii) (a) "national security" or (b) "the health and security United States citizens living abroad", and (iv) that "involves" (a) "a biological, chemical, radiological, or nuclear agent or agents" or (b) "a disease or condition that may be attributable to such agent or agents."

Similarly, the EUAs are not committed to agency discretion by law. Under § 360bbb–3(c), the Secretary "may issue an authorization" but "only if" after consultation with three other executive branch officials, he is able to make at least four different findings. Under § 360bbb–3(e), the Secretary "shall" ensure that certain "required conditions" of authorization, set forth in detail in the statute, are met. Since the Secretary does not have unfettered discretion to issue

EUAs, he must follow detailed guidance as to how any discretion granted to him by the statute is exercised. Id.

In addition to their Counts seeking judicial review of agency action and mandamus, Plaintiffs have also alleged physical injury, death and loss of employment proximately caused, aided and abetted by Defendants' actions, justifying an award of civil money damages under Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388 (1971) (Count VII). By issuing and maintaining the EUAs in these circumstances, the Defendants are enabling the shipment of the Vaccines in interstate commerce, and their use by third parties who actually administer them to the public. Defendants, as joint tortfeasors, are purposefully aiding and abetting the infliction of physical injury and death on Plaintiffs and countless other Americans, all in violation of their constitutionally protected right to personal autonomy and bodily integrity.

Guertin v. Michigan, 912 F.3d 907 (6th Cir. 2019) is a case arising out of the infamous Flint Water Crisis. 912 F.3d at 907-915. The City of Flint Michigan instituted cost-saving measures, and used outdated equipment to treat water before delivering it to residents. Id. Residents consumed the water, now contaminated with lead and *e coli* bacteria. Id. Their hair fell out and they developed rashes. Id. Some died from an associated spike in Legionnaire's disease. Id. Children tested positive for dangerously high blood levels. Id.

The 6th Circuit Court of Appeals upheld the district court's denial of defendants' motion to dismiss 42 U.S.C. § 1983 substantive due process claims based on qualified immunity, because plaintiffs had plead a plausible Fourteenth Amendment violation of their right to bodily integrity, where the City's knowing decision to use outdated equipment and mislead the public about the safety of its water shocked the conscience. Id. The Court admonished:

> ***[K]nowing the Flint River water was unsafe for public use, distributing it without taking steps to counter its problems, and assuring the public in the meantime that it was safe*** *"is conduct that would alert a reasonable person to the likelihood of liability." [ ] [T]aking affirmative steps to systematically contaminate a community through its public water supply with deliberate indifference is a government invasion of the highest magnitude. Any reasonable official should have known that doing so constitutes conscience-shocking conduct prohibited by the substantive due process clause. These "actions violate the heartland of the constitutional guarantee" to the right of bodily integrity…*

Id. at 933 (emphasis added).

The language of this decision ought to send a chill through each of the individually named Defendants, for their conduct — albeit distributing dangerous experimental Vaccines, rather than contaminated water — is effectively a mirror image. This is indisputably so with respect to the under-18 age category, and those previously infected with SARS-CoV-2. Since SARS-CoV-2 / COVID-19 present no statistically significant threat to these subpopulations, the Vaccines can have no therapeutic benefits for them. At the same time, the experimental Vaccines, which have known, dangerous side effects and in some cases are even fatal, expose them to unnecessary and dangerous risks.

B. Irreparable Injury

The test does not require that harm actually occur, or that it be certain to occur. *See* Whitaker v. Kinosha Unified School District, 858 F.3d 1034, 1044 (7th Cir. 2017). Rather, "[w]e have indicated that the injury suffered by a plaintiff is 'irreparable only if it cannot be undone through monetary remedies.'" Siegel v. LePore, 234 F.3d 1163, 1191 at Fn. 4 (11th Cir. 2000), quoting Cunningham v. Adams, 808 F.2d 815, 821 (11th Cir. 1987).

The actual or threatened violation of core constitutional rights is presumed irreparable. Id., citing *inter alia* Deerfield Med. Ctr. v. City of Deerfield Beach, 661 F.2d 328 (5th Cir. 1981) (irreparable injury presumed based on threats to access to abortion services implicating the 14th Amendment right to privacy); Robinson v. Attorney General, 957 F.3d 1171, 1177 (11th Cir.

2020) (denying motion for stay of preliminary injunction enjoining public health order issued in response to COVID-19 pandemic because it invaded constitutionally protected 14th Amendment rights); Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) ("In any event, it is the alleged violation of a constitutional right that triggers a finding of irreparable harm."); Mitchell v. Cuomo, 748 F.2d 804, 806 (2d Cir. 1984) ("'When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.'").

In Planned Parenthood v. Casey, 505 U.S. 833, 857 (1992), the U.S. Supreme Court stated:

> *Roe, however, may be seen not only as an exemplar of Griswold liberty, but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection. If so, our cases since Roe accord with Roe's view that a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims.* *Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 278, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990); cf., e. g., Riggins v. Nevada, 504 U.S. 127, 135, 118 L. Ed. 2d 479, 112 S. Ct. 1810 (1992); Washington v. Harper, 494 U.S. 210, 108 L. Ed. 2d 178, 110 S. Ct. 1028 (1990); see also, e. g., Rochin v. California, 342 U.S. 165, 96 L. Ed. 183, 72 S. Ct. 205 (1952); Jacobson v. Massachusetts, 197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905).*

To reiterate: "a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims." *See also* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) ("the 'liberty' protected by the Due Process Clause [of the Fourteenth Amendment] includes the right[] . . . to bodily integrity"); Shillingford v. Holmes, 634 F.2d 263, 265 (5th Cir.1981) ("the right to be free of state-occasioned damage to a person's bodily integrity is protected by the fourteenth amendment guarantee of due process."); Doe v. Moore, 410 F.3d 1337, 1343 (11th Cir. 2005) ("The Supreme Court has recognized that fundamental rights include those guaranteed by the Bill of Rights as well as certain 'liberty' and privacy interests implicit in the due process clause and the penumbra of constitutional rights. These special

'liberty' interests include 'the rights to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion.'").

Further, the Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the right *to obtain* medical intervention:

> *As the joint opinion acknowledges, ante, 505 U.S. at 857, this Court has recognized the vital liberty interest of persons in refusing unwanted medical treatment. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990). Just as the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment, including a woman's decision to terminate a pregnancy.*

Casey, 505 U.S. at 927.

In the Supreme Court's seminal "right to die" case, Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990), it addressed whether an individual in a persistent vegetative state could require a hospital to withdraw life-sustaining medical care based on her right to bodily integrity. 479 U.S. at 265-69. Chief Justice Rehnquist noted that "[b]efore the turn of this century, [the Supreme Court] observed that 'no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.'" Id. at 269 (quoting Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891). He continued: "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment," Id. at 269, "generally encompass[es] the right of a competent individual to refuse medical treatment," Id. at 277, and is a right that "may be inferred from [the Court's] prior decisions." Id. at 278-79 (citing Jacobson v. Massachusetts, 197 U.S. 11 (1905); Breithaupt v. Abram, 352 U.S. 432 (1957);

Washington v. Harper, 494 U.S. 210 (1990); Vitek v. Jones, 445 U.S. 480 (1980); Parham v. J.R., 442 U.S. 584 (1979).).

In Deerfield, the case relied upon by the 11th Circuit in Siegel, a medical group attempted to establish a medical facility to provide abortion services. 661 F.2d at 330-332. The city denied their application for an occupational license on various grounds. Id. The medical group sued the city alleging that the city's actions violated the "right to privacy" in the due process clause of the 14th Amendment by depriving women of access to abortion services, even though any potential constitutional violation was minimized by the presence of other abortion facilities operating in the area. Id. The medical group moved for a preliminary injunction, and the district court denied the motion. Id.

The 5th Circuit reversed, adopting an aggressive, prophylactic approach to the protection of the constitutional right to privacy. "[T]he right of privacy must be carefully guarded for once an infringement has occurred it cannot be undone by monetary relief." Id. at 338, citing to Kennan v. Nichol, 326 F. Supp. 613, 616 (W.D.Wis.1971), aff'd mem., 404 U.S. 1055, 92 S. Ct. 735, 30 L. Ed. 2d 743 (1972) ("to withhold a temporary restraining order is to permit the (constitutional right of privacy) to be lost irreparably with respect to the physician and those women for whom he would otherwise perform the operation in the meantime."). It continued: "We have already determined that the constitutional right of privacy is 'either **threatened** or in fact being impaired', and **this conclusion mandates a finding of irreparable injury**" (emphasis added). Id. at 338, citing to Elrod v. Burns, 427 U.S. 347, 373 (1976).

The Defendants are both violating, and threatening the violation of, the core constitutional right to personal autonomy and bodily integrity held by Plaintiffs and all Americans. Plaintiffs Brittany Galvin (*see* Declaration of Brittany Galvin at Exhibit J), Aubrey Boone, Snow Mills, Angelia Deselle (*see* Declaration of Angelia Deselle at Exhibit H), Kristi

Simmonds, Vidiella A/K/A Shawn Skelton (*see* Declaration of Shawn Skelton at Exhibit I) and the Estate of Dovi Sanders Kennedy have alleged that their rights to personal autonomy and bodily integrity were violated when they were subjected to Vaccines without first having given voluntary, informed consent. Plaintiffs have also attached the Declaration of Diana Hallmark, a resident of Blount County, Alabama, containing the same allegations (*see* Declaration of Diana Hallmark at Exhibit K).[51] These victims testify under penalty of perjury to their physical injuries caused by the Vaccines, and to facts and circumstances that establish that they did not give, and could not possibly have given, their voluntary, informed consent. By way of example, Plaintiff Deselle states (Ex. H):

> *No one ever provided me with any information regarding possible adverse reactions, nor did they provide me with any information regarding alternative treatments. I did not understand this was gene therapy rather than a traditional vaccine. Again, I also did not understand that the Vaccines were not "approved" by the FDA. No one told me, and I did not understand that the Vaccines were not determined to be "safe and effective" by anyone — only that it was "reasonable to believe" that they were.*

In addition to constitutional infringements, physical injury and death may constitute irreparable harm justifying preliminary injunctive relief. *See* Chastain v. Northwest Ga. Hous. Auth., 2011 U.S. Dist. LEXIS 135712 (N.D. Ga. 2011) (possibility of worsening health following eviction from public housing); Garcia v. Google, Inc., 766 F.3d 929, (9th Cir. 2014), aff'd on rehearing en banc, 786 F.3d 733 (9th Cir. 2015) ("[I]t is not irrelevant that the harm Garcia complains of is death or serious bodily harm, which the dissent fails to mention. Death is an 'irremediable and unfathomable' harm, and bodily injury is not far behind. To the extent the irreparable harm inquiry is at all a close question, we think it best to err on the side of life."); Seniors Civil Liberties Ass'n v. Kemp, 761 F.Supp. 1528, 1537 (M.D. Fla. 1991) (possibility of

[51] Plaintiffs anticipate amending the Complaint for the purpose of *inter alia* adding Diana Hallmark to it as a named Plaintiff.

physical injury or death arising from police chokeholds). Plaintiffs Brittany Galvin (Ex. J), Aubrey Boone, Snow Mills, Angelia Deselle (Ex. H), Kristi Simmonds, Vidiella A/K/A Shawn Skelton (Ex. I) and the Estate of Dovi Sanders Kennedy have alleged that the Vaccines have caused them grave physical injury and, in the case of Dovi Sanders, also death. Diana Hallmark has made the same allegations (Ex. K).

The court may consider the harm to the public in assessing whether irreparable injury would result from the denial of an injunction. In Hornbeck Offshore Servs., LLC v. Salazar, 696 F.Supp. 2d 627 (E.D. La. 2010) the court granted a motion for preliminary injunction enjoining a federal agency decision to suspend drilling operations in the Gulf of Mexico, finding irreparable harm based on the harm to the public generally:

> *The defendants trivialize [Plaintiffs' losses] by characterizing them as merely a small percentage of the drilling rigs affected [ ] [C]ourts have held that in making the determination of irreparable harm, "both harm to the parties and to the public may be considered. The effect on employment, jobs, loss of domestic energy supplies caused by the moratorium as the plaintiffs (and other suppliers, and the rigs themselves) lose business, and the movement of the rigs to other sits around the world will clearly ripple throughout the economy in this region.*

696 F.Supp. 2d at 638-639 (internal citations omitted).

In In re Northwest Airlines Corp., 349 B.R. 338, 384 (S.D.N.Y. 2006), aff'd, 483 F.3d 160 (2d Cir. 2007), the court granted a motion for preliminary injunction enjoining a flight attendants' union from carrying out threats to engage in a labor strike, finding irreparable harm based on the harm to the public generally:

> *"[I]n making the determination of irreparable harm, both harm to the parties and to the public may be considered."* * * Here, the record also demonstrates that the public will be harmed: as the Bankruptcy Court found, Northwest carries 130,000 passengers per day, has 1,200 departures per day, is the one carrier for 23 cities in the country, and provides half all airline services to another 20 cities.*

349 B.R. at 384 (quoting Long Island R. Co. v. Int'l Ass'n of Machinists, 874 F.2d 901, 910 (2d Cir. 1989)).

Like Plaintiffs Brittany Galvin (Ex. J), Aubrey Boone, Snow Mills, Angelia Deselle (Ex. H), Kristi Simmonds, Vidiella A/K/A Shawn Skelton (Ex. I), and the Estate of Dovi Sanders Kennedy, and like Diane Hallmark (Ex. K), millions of Americans have already suffered an outrageous violation of their constitutionally protected right to personal autonomy and bodily integrity, and millions more are vulnerable. According to the VAERS data, there have been 438,441 reported adverse events following injection with the Vaccines, including 9,048 deaths and 41,015 serious injuries, between December 14, 2020 and July 2, 2021. The evidence suggests the VAERS system reports only between 0.8% and 2% of all Vaccine adverse events. Plaintiffs' expert and whistleblower Jane Doe has testified that the true number of deaths caused by the Vaccines is at least 45,000 not the approximately 9,000 reported by VAERS (*see* Declaration at Ex. D). By contrast, the Swine Flu vaccine was removed from the market even though it caused only 53 deaths.

C. Balance of Equities (Hardships) and Public Interest

In each case involving a request for pretrial injunctive relief, the court "must consider the effect on each party of the granting or withholding of the requested relief." Winter, 555 U.S. at 24. The plaintiff "must establish . . . that the balance of hardships tips in his favor." Id. at 20.

"'[W]here the government is the party opposing the preliminary injunction, its interest and harm merge with the public interest.' Thus the Court proceeds with analyzing whether the threatened injury to Plaintiffs outweighs the harm that the preliminary injunction would cause Defendants and the public." Brown v. Azar, 497 F. Supp. 3d 1270, 1298 (N.D. Ga. 2020), quoting Swain v. Junior, 958 F.3d 1081, 1091 (11th Cir. 2020).

"[I]t is always in the public interest to prevent the violation of a party's constitutional rights." G & V Lounge, Inc. v. Mich. Liquor Control Comm'n, 23 F.3d 1071, 1079 (6th Cir. 1994). "The vindication of constitutional rights and the enforcement of a federal statute serve the public interest almost by definition." League of Women Voters of Fla. v. Browning, 863 F. Supp. 2d 1155, 1167 (N.D. Fla. 2012). On the other hand, "[t]here is generally no public interest in the perpetuation of unlawful agency action." League of Women Voters v. Newby, 838 F.3d 1, 12 (D.C. Cir. 2016).

Defendants themselves suffer no conceivable harm from the grant of the requested injunctions. A disease that has an overall survivability rate exceeding 99% — comparable to the seasonal flu and countless other ailments — does not create a public health emergency within the meaning of § 360bbb–3. SARS-CoV-2 and COVID-19 do not give rise to any countervailing public interest that justifies overriding the constitutionally protected right to personal autonomy and bodily integrity. This is so with respect to the entire American public, but even more acutely with respect to the under-18 age category and those previously infected with SARS-CoV-2.

IV. CONCLUSION

Accordingly, and for all of the foregoing reasons, Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called "Pfizer-BioNTech COVID-19 Vaccine," "Moderna COVID-19 Vaccine" and the "Johnson & Johnson (Janssen) COVID-19 Vaccine" pursuant to their respective EUAs, and from granting full FDA approval of the Vaccines:

(i) for the under-18 age category;

(ii) for those, regardless of age, who have been infected with SARS-CoV-2 prior to vaccination; and

(iii) until such time as the Defendants have complied with their obligation to create and maintain the requisite "conditions of authorization" under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb–

3(e), thereby enabling Vaccine candidates to give truly voluntary, informed consent.

Dated: July 19, 2021.

RESPECTFULLY SUBMITTED BY:

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CERTIFICATE OF SERVICE

I hereby certify that on this date, July 19, 2021, I electronically transmitted this pleading to the Clerk of the Court using the CM/ECF system for filing, which will send notification of such filing to the following counsel for the Defendants:

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